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Achaogen, Inc.

Fourth-Quarter Financials Nonevent; Update on CARE Study Protocol Next

On Monday, March 16, after markets closed, Achaogen reported fourth quarter and full year 2014 financial results (exhibit 1). The company ended the year with $63.7 million in cash, which should sustain operations through the data readout from Phase III CARE study expected in 2017, according to our model. Net loss for the quarter was $4.9 million versus our estimate of $8.4 million and consensus of $5.9 million. Per share loss was $0.27, beating our estimates of $0.47 and consensus of $0.33. We updated our model as illustrated in exhibit 1.

The pivotal Phase III CARE (Combating Antibiotic-Resistant Enterobacteriaceae) study has been enrolling more slowly than expected, and management reiterated that Achaogen had been in discussions with regulatory authorities to potentially modify the CARE study protocol to speed up enrollment. Achaogen is expected to provide an update early in second quarter 2015. The Phase III CARE study is currently designed to evaluate the company's lead asset, plazomicin, for the treatment of bloodstream infections (BSI) and nosocomial pneumonia caused by carbapenem-resistant Enterobacteriaceae (CRE). Most sites in the United States and Europe are up and running; locations in Latin America came online in first quarter 2015, and all sites, including in Asia, are expected to be active during first half 2015.

In January 2015, Achaogen announced that plazomicin received Qualified Infectious Disease Product (QIDP) designation from the FDA. QIDP designation will provide plazomicin with priority review, shortening the amount of time from New Drug Application (NDA) submission to potential regulatory approval, and will also provide plazomicin an additional five years of market exclusivity.

Key upcoming catalysts for the company include: Top-line data from the Phase III CARE study are expected in 2017; however, two interim analyses expected in second half 2015 and second half 2016 will act as key catalysts over the next several years along with top-line data from the Phase II supportive study around second quarter 2016. Regulatory filing for plazomicin is expected in the second half of 2017, and we anticipate U.S. approval by the FDA during second half 2018. We illustrate plazomicin's development timeline in exhibit 3.

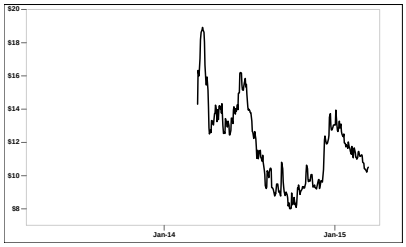
Stock Rating:	**Outperform**
Company Profile:	**Aggressive Growth**
Price Target:	$25.00
Symbol:	AKAO (NASDAQ)
Price:	$10.05 (52-Wk.: $8-$20)
Market Value (mil.):	$178
Fiscal Year End:	December
Long-Term EPS Growth Rate:	
Dividend/Yield:	None

	2013A	2014A	2015E
Estimates			
EPS Q1	NA	$-1.00	$-0.30
Q2	NA	$-0.20	$-0.29
Q3	NA	$-0.47	$-0.29
Q4	NA	$-0.27	$-0.30
FY	$-1.36	$-1.42	$-1.18
CY		$-1.42	$-1.18
Sales (mil.)	NA	20	17
Valuation			
FY P/E	NM	NM	NM
CY P/E		NM	NM

Trading Data (FactSet)	
Shares Outstanding (mil.)	18
Float (mil.)	6
Average Daily Volume	67,914

Financial Data (FactSet)	
Long-Term Debt/Total Capital (MRQ)	0.0
Book Value Per Share (MRQ)	3.8
Return on Equity (TTM)	0.0

Two-Year Price Performance Chart



Sources: FactSet, William Blair & Company estimates

Achaogen, Inc., a biopharmaceutical company based in South San Francisco, California, focuses its research-and-development efforts on novel antibacterials to treat multi-drug-resistant, Gram-negative infections.

We maintain our Outperform rating and $25 price target (exhibit 2) ahead of the regulatory update on CARE. Our Outperform rating is centered on our belief that Achaogen's lead asset, plazomicin, will become the standard of care for the treatment of bloodstream infections and pneumonia caused by CRE infection, and could generate peak worldwide sales of $370 million by 2028. In our probability adjusted NPV model, we expect plazomicin to reach the market by 2018 with a probability of success of 70% and become the market leader in the treatment of CRE infections. We currently assume peak penetration of plazomicin at about 70%, both in the United States and in Europe, based on our expectation that plazomicin obtains a favorable label regarding superiority in survival benefit for the indication. We assume plazomicin will be priced at $16,000 and $14,000 per course of therapy at launch in the United States and Europe, respectively. We therefore derive U.S. peak sales of about $290 million in 2031 and approximately $100 million in Europe in 2028, with peak worldwide sales of roughly $370 million in 2028. We currently assign plazomicin $23 per share in valuation, with $17 associated with its commercial prospects in the United States and $6 in Europe. Combining our valuation for plazomicin with net cash of approximately $2 per share at year-end 2015, we derive our 12-month price target of $25. Potential sources of upside to our revenue estimates include: 1) empirical use of plazomicin, which could add an additional $100 million in sales in 2028; 2) upside to net U.S. pricing; and 3) sales of plazomicin in territories outside the United States and Europe.

Key risks to our Outperform rating and price target include: 1) Phase III study assumptions are based on a meta-analyses of mortality in patients with carbapenemase-producing Enterobacteriaceae (CPE) in addition to in vitro and in vivo animal studies; 2) no prospective study has been conducted on the effects of plazomicin in patients with CRE-related BSIs or pneumonia; 3) serious adverse events may increase with exposure; 4) enrollment is hard to track and estimate because the target population is rare; 5) the CRE market may be smaller than expected and may be difficult to penetrate; 6) a companion diagnostic from ARK Diagnostics is required that must also receive regulatory approval; 7) if highly priced, reimbursement may be difficult or hindered; and 8) financing risk exists.

Review of Key Points From Phase III CARE Study as Currently Designed

We note that this is the first pathogen-specific pivotal study that strives for superiority in overall survival as the primary endpoint. We believe that should such a label be obtained, plazomicin would be favored over other antibiotics in the battle against CRE and command premium pricing.

- ***Phase III CARE study design.*** The 360-patient, randomized, open-label study compares efficacy and safety of plazomicin against colistin in patients with bloodstream infections (BSIs) or hospital-acquired pneumonia resulting from CRE versus standard of care. Patients who are infected with either presumed or confirmed pathogen that exhibit MIC of 4 μg/mL or greater against the broadest spectrum carbapenems will be enrolled and randomized in a 1:1 fashion to either the plazomicin- or colistin-based regimen. Patients are allowed one adjunctive antibiotic, either tigecycline or meropenem, at the time of randomization, at the discretion of the investigator. The treatment duration is 7 to 14 days. All-cause mortality, the primary endpoint, will be assessed at day 28, and late safety follow up is planned at day 60. Secondary endpoints include time to death, microbiological and clinical responses, resolution of fever, and improvement in oxygenation for pneumonia patients, safety, and pharmacoeconomic assessments. The study includes two unblinded interim analyses of efficacy and futility; the two interim analyses are to occur when 33% and 67% of patients have reached day 28 (the end of the study), which is projected to occur in the end of 2015 and the end of 2016, respectively. Top-line data from the study is expected in the first half of 2017, pending successful study enrollment.

While we believe plazomicin is a viable antibiotic for the treatment of CRE, several arguments must be taken into consideration when assessing its overall likelihood of success. Several of our rationales for assigning the program a 70% probability of success include:

- ***The potency of plazomicin in CRE is based on in vivo and in vitro studies, as discussed above; translation to humans is predicted but needs to be demonstrated.*** While plazomicin is comparable to levofloxacin for safety and efficacy in cUTIs, there are no prior dedicated studies investigating the effects of plazomicin in CRE. Although we are relatively confident that efficacy of antibacterials generally translates from in vivo models to the clinic, it still needs to be demonstrated in this case. We note that Achaogen will initiate a supporting single-arm Phase II study in CRE in 2015 and data should read out in 2016. This study could provide data on plazomicin's activity in CRE and if successful should create heightened excitement and confidence in the ongoing Phase III CARE study.

- ***Phase III enrollment is projected to take three years, but the emerging epidemiology is a moving target.*** The incidence of CRE has been increasing over the past few years especially in certain hotspot areas; however, the exact timeline of enrollment is difficult to predict as the epidemiology data is still developing.

- ***The statistical assumptions for the Phase III study are based on a meta-analysis of three observational studies.*** There is limited data in literature on mortality rates from CRE and as discussed in detail herein, the Phase III study is based on a meta-analysis describing mortality outcomes from 309 patients infected with carbapenemase-producing Enterobacteriaceae. The meta-analysis classified outcomes of these patients into two groups: resistant or sensitive to carbapenems, and observed that the absolute mortality difference between the two groups was 21% (60% relative difference). Based on such data, the underlying assumption for the CARE study is that plazomicin treatment should afford patients a similar mortality benefit to those in the sensitive group in the meta-analysis, which is a 21% absolute mortality reduction from the current standard of care.

- ***Although the Phase III study design is based on a meta-analysis, a margin of safety is built in, thereby increasing the probability of success, in our opinion.*** The Phase III study is powered at 70% to detect an absolute reduction in mortality of 12% (35% relative reduction). This assumptions appear conservative as compared with the observed mortality reduction of 21% (60% relative reduction) demonstrated by the meta-analysis. This difference allows for a reasonable margin of safety, thus increasing the probability of success, in our opinion.

- ***Interim analyses are built in to provide a potential opportunity to adjust sample size if necessary, ensuring power of the study.*** There will be two unblinded interim analyses occurring when 33% and 67% of the patients in the study have reached day 28 (the end of the study). A data monitoring committee will review the data and determine if the study should be stopped based on efficacy or futility. These interim analyses might also help determine whether more patients will need to be enrolled to ensure power of the study.

- ***A companion diagnostic will be employed to ensure plazomicin plasma and lung concentration reaches bactericidal levels, thereby ensuring maximum efficacy in every patient.*** Since plazomicin is renally excreted, dosing will be individually optimized using a diagnostic to ensure sufficient drug plasma and lung concentration to combat infections. Pharmacometric modeling developed at Achaogen predicts that 92% of patients should be able to achieve sufficient drug levels in the blood or the lung that are effective against their CRE infection.

- ***Phase III study is enriched with patients who will most likely see a mortality benefit from plazomicin treatment.*** To better assess mortality in terms of disease severity, all patients will be evaluated using the APACHE II score, which ranges from 0 to 71, with 71 being most severe. Enrolled patients will have APACHE II scores ranging from 15 to 30. We highlight this because it ensures that enrolled patients are neither too healthy nor too sick, increasing the odds of demonstrating a mortality benefit.

- ***The safety profile remains to be evaluated when used for a longer duration of treatment in a sicker patient population.*** While the Phase II study in cUTI demonstrated a safe and tolerable profile for 5 days of treatment, the safety profile needs to be further evaluation in the Phase III study where treatment duration is increased to 7-14 days, and the patient population is much sicker. Undoubtedly, the risk/benefit profile will be different in this sicker population, with patients and regulators willing to accept greater risk if a significant mortality benefit is demonstrated.

- ***High risk, high reward: The primary endpoint of mortality is bold and novel to antibiotics.*** Unlike other antibiotics, the registrational trial will strive for superiority in survival. Should such a label be obtained, plazomicin should be preferentially used in the labeled indication, and command premium pricing, in our opinion.

Exhibit 1
Achaogen, Inc.
Income Statement
(dollars in thousands)

	2012A	2013A	2014E					2015E	2016E
	FY:12A	FY:13A	Q1A	Q2A	Q3A	Q4A	FY:14A		
Revenues									
Plazomicin US revenues	$0	$0	$0	$0	$0	$0	$0	$0	$0
Plazomicin OUS royalties	-	-	-	-	-	-	-	-	-
Collaboration and licensing revenue	-	-	-	-	-	-	-	-	-
Contract and grant revenue	17,941	18,512	5,988	5,203	4,520	4,259	19,970	17,036	24,000
Total Revenues	**17,941**	**18,512**	**5,988**	**5,203**	**4,520**	**4,259**	**19,970**	**17,036**	**24,000**
Expenses									
COGS	-	-	-	-	-	-	-	-	-
R&D expense	26,581	23,484	6,605	6,195	10,678	6,632	30,110	27,330	28,437
SG&A expense	7,349	6,992	2,617	2,346	2,175	2,508	9,646	10,693	11,567
Total Operating Expenses	33,930	30,476	9,222	8,541	12,853	9,140	39,756	38,022	40,004
Operating Income	(15,989)	($11,964)	(3,234)	(3,338)	(8,333)	(4,881)	(19,786)	(20,986)	(16,004)
Interest income	51	193	-	-	-	-	-	40	136
Interest expense, net	(2,427)	(1,341)	(221)	(217)	21	-	(417)	(231)	-
Other (expense) income, net			-	-	-	27	27	-	-
Total Other Income (Expense)	(18,365)	(13,112)	(3,455)	(3,555)	(8,312)	(4,854)	(20,176)	(21,177)	(15,868)
Pretax income/(loss)	(18,365)	(13,112)	(3,455)	(3,555)	(8,312)	(4,854)	(20,176)	(21,177)	(15,868)
Other comprehensive gain/(loss)	-	-	-	-	-	-	-	-	-
Provision for income taxes/(income)	-	-	-	-	-	-	-	-	-
Net Income/(Loss)	**($18,365)**	**($13,112)**	**($3,455)**	**($3,555)**	**($8,312)**	**($4,854)**	**($20,176)**	**($21,177)**	**($15,868)**
GAAP EPS		**($1.36)**	**($1.00)**	**($0.20)**	**($0.47)**	**($0.27)**	**($1.42)**	**($1.18)**	**($0.76)**
Weighted average shares outstanding, diluted		9,673	3,456	17,691	17,711	17,786	14,210	17,973	20,961

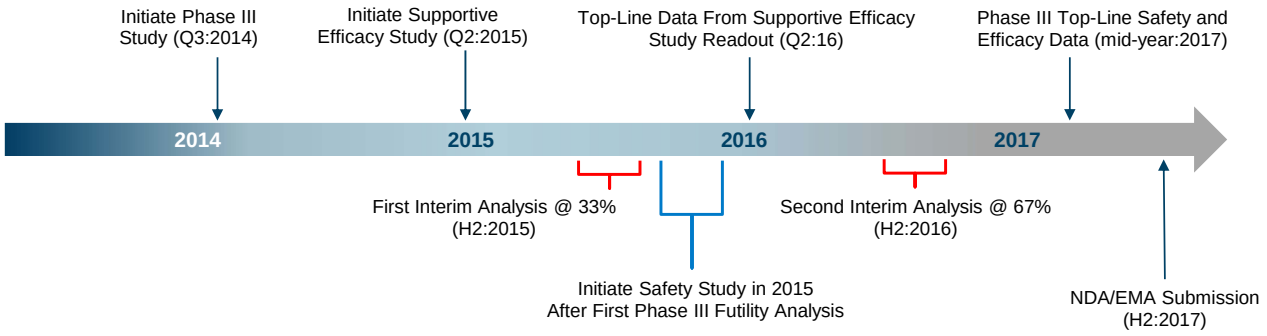
Sources: Achaogen, Inc. and William Blair & Company, L.L.C. estimates

Exhibit 2
Achaogen, Inc.
Sum-of-the-Parts Fair Value
(dollars in thousands, except shares)

Drug	Peak Sales	Stage of Development	Estimated Launch Date	Probability of Commercialization	Percentage of Sales to Company	Probability-Adjusted NPV	Value per Share	Percentage of Fair Value
Plazomicin—United States	$289,456	Phase III	H2:2018	70%	100%	$302,970	$16.75	65.8%
Plazomicin—Europe	$99,128	Phase III	H1:2019	70%	30% Royalty	$115,942	$6.41	25.2%
Subtotal						**$418,911**	**$23.16**	**91.0%**
Net Cash at Year-End 2015						$46,187	$2.55	10.0%
Net Present Value of additional Gain (Loss)*						($5,000)	($0.28)	(1.1%)
Sum-of-Parts Fair Value						**$460,098**	**$25.44**	**100.0%**

* Includes costs not directly related to programs above
Sources: Company reports and William Blair & Company, L.L.C. estimates

Exhibit 3
Achaogen, Inc.
Plazomicin Development Timeline



Sources: Achaogen, Inc. and William Blair & Company, L.L.C.

IMPORTANT DISCLOSURES

William Blair was a manager or co-manager of a public offering of equity securities for Achaogen, Inc. within the prior 12 months.

William Blair is a market maker in the security of Achaogen, Inc.

William Blair intends to seek investment banking compensation in the next three months from Achaogen, Inc.

Within the past 12 months William Blair has provided or is providing investment banking services to or has an investment services relationship with Achaogen, Inc.

Additional information is available upon request.

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DOW JONES: 17,977.42
S&P 500: 2,081.19
NASDAQ: 4,929.51

Current Rating Distribution (as of 02/28/15)

Coverage Universe	Percent	Inv. Banking Relationships*	Percent
Outperform (Buy)	65	Outperform (Buy)	16
Market Perform (Hold)	32	Market Perform (Hold)	2
Underperform (Sell)	2	Underperform (Sell)	0

*Percentage of companies in each rating category that are investment banking clients, defined as companies for which William Blair has received compensation for investment banking services within the past 12 months.

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