Achaogen, Inc. (AKAO - \$9.03 - NASDAQ) More Support From DC - Raising to Buy

<u>Year</u> 2016P	<u>EPS</u> (\$1.00)	<u>PMV</u> \$19	Dividend: None Current Return: Nil			
2015P	(1.20)	19	Shares O/S: 17.7 million			
2014E	(1.60)	18	52-Week Range: \$19.69 - \$8.62			
2013A	(1.36)					

COMPANY OVERVIEW

Achaogen, headquartered in South San Francisco, CA, is a clinical stage pharmaceutical company developing plazomicin, a novel aminoglycoside antibiotic. Plazomicin is currently in Phase III for the treatment of carbapenem-resistant *Enterobacteriaceae* (CRE) infections. The company went public in March 2014 at an IPO price of \$12 per share.

Reason For Comment

On September 18, 2014, the Obama administration announced a comprehensive set of new federal actions to combat the rise of antibiotic-resistant bacteria. We believe that Achaogen could see the greatest benefit from this initiative among the companies with late-stage antibiotics in development. Highlights from the report by the President's Council of Advisors on Science and Technology (PCAST) include:

- *More funding for everything.* PCAST calls for additional funding to support resistance surveillance, antibiotic stewardship, and both early-stage and clinical development work. It estimates that BARDA would require \$800 million of annual funding to support one new drug approval each year. We would expect this to help secure Achaogen's committed BARDA funding (\$103.8M) and potentially increase this amount.
- Faster development timelines. In addition to increased development funding, PCAST suggests accelerated development timelines, especially for narrow-spectrum drugs like plazomicin that target particularly difficult-to-treat bacteria like CRE. Achaogen recently enrolled the first patient in its Phase III trial, but results from the study are not expected until late 2017. By increasing bacteria strain surveillance and pooling enrollment across multiple trials (similar to recent efforts in oncology), these proposed new initiatives could provide potential upside to our timeline estimates for plazomicin.
- Economic incentives. While development support would be a 'push' mechanism, PCAST also outlined three 'pull' mechanisms that would provide economic incentives for approved antibiotics. These included higher reimbursement rates, 'delinkage' (separating antibiotic usage from revenues through government payouts), and tradable vouchers to extend market exclusivity for another drug. PCAST acknowledges that these ideas are likely to be controversial and difficult to implement, but we note its general willingness to recognize the value of new antibiotics and accept higher prices/costs to support them. In particular, PCAST estimated that incentive payments would need to be in the range of \$400M while complete buyouts would be closer to \$1B per drug. Based on these incentives, we believe that PCAST would be supportive of a premium pricing model for plazomicin, and any economic incentives would be positive catalyst for the antibiotic sector.

Raising to Buy

Achaogen shares have fallen by 41% in the past two months since our initiation, compared to an average 4% gain for the other antibiotic pure-plays. We believe that this is an attractive entry point for AKAO shares. Plazomicin is still the highest risk program among antibiotic peers, but we also believe that it has the greatest potential upside from increased government support, accelerated development timelines, and acceptance of premium pricing. Achaogen currently has \$74.5M of cash (\$4.20 per share), a relatively low burn rate (~\$5M per quarter) due to BARDA funding, and a \$114M NOL carryforward. In a consolidating specialty pharmaceutical market, we believe Achaogen could be a target for an established antibiotic company seeking a specialized asset with the opportunity for premium pricing. AKAO currently trades at a 52% discount to our 2015 PMV of \$19 per share.

Table 1

Achaogen Inc. **Private Market Value Analysis** 2014E - 2020P

(\$ in millions except per share data)	<u>2014E</u>	2015P	2016P	<u>2017P</u>	2018P	2019P	<u>2020P</u>
Product Revenue					\$ 25	\$ 51	\$ 80
Valuation Multiple							8.5 x
Annual Discount	10%	10%	10%	10%	10%	10%	
Total Private Market Value	384	422	464	511	562	618	680
Clinical Stage Discount	35%	35%	35%	20%			
Risk-Adjusted Total PMV	\$ 249	\$ 274	\$ 302	\$ 409	\$ 562	\$ 618	\$ 680
Less: Net Debt	58	37	21	(4)	(21)	(28)	(10)
Plus: NOL (a)	27	31	34	38	42	44	42
Less: Option Payments (b)	(12)	(12)	(13)	(18)	(26)	(29)	(33)
Equity Private Market Value	\$ 322	\$ 330	\$ 343	\$ 425	\$ 557	\$ 605	\$ 679
Shares Outstanding	18	18	18	18	18	18	18
PMV per share	\$18	\$19	\$19	\$24	\$31	\$34	\$38
Current Market - Discount to PMV	50%	52%	52%	62%	71%	73%	76%

⁽a) Net present value of federal NOL carryforward

Source: Company filings and Gabelli & Company estimates

I, Kevin Kedra, the Research Analyst who prepared this report, hereby certify that the views expressed in this report accurately reflect the analyst's personal views about the subject companies and their securities. The Research Analyst has not been, is not and will not be receiving direct or indirect compensation for expressing the specific recommendation or view in this report.

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Important Disclosures

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Analysts' ratings are largely (but not always) determined by our "private market value," or PMV methodology. Our basic goal is to understand in absolute terms what a rational, strategic buyer would pay for an asset in an open, arms-length transaction. At the same time, analysts also look for underlying catalysts that could encourage those private market values to surface.

A Buy rated stock is one that in our view is trading at a meaningful discount to our estimated PMV. We could expect a more modest private market value to increase at an accelerated pace, the discount of the public stock price to PMV to narrow through the emergence of a catalyst, or some combination of the two to occur.

A Hold is a stock that may be trading at or near our estimated private market value. We may not anticipate a large increase in the PMV, or see some other factors at work.

A Sell is a stock that may be trading at or above our estimated PMV. There may be little upside to the value, or limited opportunity to realize the value. Economic or sector risk could also be increaseing.

We prepared this report as a matter of general information. We do not intend for this report to be a complete description of any security or company and it is not an offer or solicitation to buy or sell any security. All facts and statistics are from sources we believe to be reliable, but we do not guarantee their accuracy. We do not undertake to advise you of changes in our opinion or information. Unless otherwise noted, all stock prices reflect the closing price on the business day immediately prior to the date of this report. We do not use "price targets" predicting future stock performance. We do refer to "private market value" or PMV, which is the price that we believe an informed buyer would pay to acquire 100% of a company. There is no assurance that there are any willing buyers of a company at this price and we do not intend to suggest that any acquisition is likely. Additional information is available on request.

As of August 31, 2014 our affiliates beneficially own on behalf of their investment advisory clients or otherwise less than 1% of Achaogen. Because the portfolio managers at our affiliates As of Adagst 17, 2014 on a lithiates belieflicianly own of behalf of their investment avisory criefles of outerwise less until 17,001 Adagst. It is betals the portfolio managers are with respect to the client accounts they manage, these accounts may have transactions inconsistent with the recommendations in this report. These portfolio managers may know the substance of our research reports prior to their publication as a result of joint participation in research meetings or otherwise. The analyst who wrote this report may receive commissions from our customers' transactions in the securities mentioned in this report. Our affiliates may receive compensation from the companies referred to in this report for non-investment banking securities-related services, or may be soliciting these companies as clients for non-investment banking securities-related services. The analyst that wrote this report, or members of his household, owns no shares of Achaogen, Inc

⁽b) After-tax payments to buy out options at PMV