ACHAOGEN

May 8, 2017

Achaogen Reports First Quarter 2017 Financial Results and Provides Corporate Update

-- Presented additional Phase 3 EPIC and CARE trial data highlighting the safety and efficacy of plazomicin during late-breaker session at ECCMID --

-- Plazomicin registration activities on track; NDA submission planned for the second half of 2017 --

-- Conference call today at 4:30 p.m. Eastern Time --

SOUTH SAN FRANCISCO, Calif., May 08, 2017 (GLOBE NEWSWIRE) -- Achaogen, Inc. (NASDAQ:AKAO), a late-stage biopharmaceutical company discovering and developing innovative antibacterials addressing multi-drug resistant (MDR) gram-negative infections, today reported financial results for the first quarter 2017, and provided an update on its corporate and clinical development activities.

"Advancing plazomicin registration activities is our top priority; we are encouraged by our progress with manufacturing and had a productive pre-NDA meeting with FDA in April. We remain on track with our plans to file the plazomicin NDA in the second half of 2017," said Kenneth Hillan, M.B. Ch.B., Achaogen's Chief Executive Officer. "We have made excellent progress with our C-Scape program and plan to initiate a Phase 1 clinical trial in the second quarter of 2017."

Recent Highlights and Upcoming Milestones

Plazomicin has successfully completed two Phase 3 clinical trials and the Company plans to submit a New Drug Application (NDA) to the Food and Drug Administration (FDA) in the second half of 2017 and to submit a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in 2018. The EPIC (**E**valuating **P**lazomicin **I**n **c**UTI) trial is expected to serve as a single registration trial supporting an NDA for plazomicin in the United States and an MAA in the European Union. The second study, the Phase 3 CARE (**C**ombating **A**ntibiotic **R**esistant **E**nterobacteriaceae) trial was a resistant pathogen trial designed to evaluate the efficacy and safety of plazomicin in patients with serious bacterial infections due to carbapenem-resistant Enterobacteriaceae (CRE) and provides additional data supporting the NDA and plazomicin therapy in these patients.

- Last month, the Company announced newly-presented plazomicin data at the European Congress of Clinical Microbiology and Infectious Disease (ECCMID) that highlighted the efficacy of plazomicin against MDR gram-negative bacteria in clinical and non-clinical settings:
  - Phase 3 EPIC trial data demonstrated superior microbiological eradication rates at test-of-cure, including higher microbiological eradication rates against key resistant pathogens for plazomicin compared to meropenem;
  - Phase 3 EPIC trial data demonstrated a lower rate of clinical relapse in patients receiving plazomicin compared to meropenem;
  - Phase 3 CARE trial data showed lower 28-day all-cause mortality that was maintained through Day 60 for plazomicin compared to colistin in patients with serious bloodstream infections (BSI) due to CRE; and
  - Plazomicin demonstrated potent *in vitro* activity against isolates containing the plasmid-encoded colistin resistance (mcr-1) gene.
- During the quarter, in a data presentation at the Society for Healthcare Epidemiology in America (SHEA) Spring 2017 Conference, a multi-center, multi-year analysis of CRE burden in the U.S. suggested that CRE is rapidly increasing, with an estimate of more than 65,000 CRE infections in 2015.

C-Scape — Achaogen is developing an orally-available antibacterial candidate, C-Scape, that is a combination of an approved beta-lactam and an approved beta-lactamase inhibitor, with the potential to treat patients with cUTI due to MDR pathogens such as extended spectrum beta-lactamase (ESBL) producing *Escherichia coli* and *Klebsiella pneumoniae*.

- Achaogen is currently projecting to commence C-Scape clinical development in the second quarter of 2017 and, if successful, to proceed to pivotal Phase 3 cUTI trial initiation in the first half of 2018.
  - Company met with FDA during the quarter; plans to leverage a 505(b)(2) regulatory path involving a single pivotal trial.
- In January 2017, C-Scape was awarded qualified infectious disease product (QIDP) status by FDA for the treatment of cUTI, including acute pyelonephritis

Other Corporate Highlights

- Entered into a collaboration with the Bill & Melinda Gates Foundation for up to $20.5 million to accelerate the development of Achaogen's unique antibody discovery platform and to initially support the discovery of monoclonal antibody candidates targeting *Acinetobacter baumannii*, a leading cause of neonatal sepsis and a major focus of Achaogen's internal bactericidal antibody program.

First Quarter 2017 Financial Results

Unrestricted cash, cash equivalents and short-term investments totaled $132.0 million at March 31, 2017 compared to $145.9 million at December 31, 2016.

Contract revenue totaled $7.5 million for the first quarter of 2017 compared to $5.8 million for the same period of 2016. The increase in contract revenue during the quarter was primarily due to the increased research and development activities under the contract Option 3 with BARDA. As of March 31, 2017, $0.1 million and $0.6 million remains on the BARDA and NIAID contracts, respectively. Achaogen derived all of its revenue from funding provided under U.S. government contracts in connection with the research and development of product candidates.

Research and development (R&D) expenses were $18.6 million for the first quarter of 2017 compared to $13.9 million reported for the same period in 2016. The increase in R&D expenses during the first quarter were attributable to: a) concluding the plazomicin clinical trials and initiation of engineering and validation manufacturing campaigns, b) initiation of the C-Scape program, and c) continued advancement of the Company's earlier stage pipeline.

General and Administrative (G&A) expenses were $6.8 million for the first quarter of 2017 compared to $3.8 million for the same period in 2016. The increase in G&A expenses was primarily attributable to higher personnel related expenses and increased activity to prepare for registration and potential commercialization of plazomicin.

Change in warrant and derivative liabilities were $15.0 million for the first quarter of 2017 compared to nil for the same period in 2016. The increase was primarily related to non-cash charges for the revaluation of warrants issued in the private placement of common stock and warrants to purchase common stock in June 2016.

Net loss for the first quarter of 2017 was $33.3 million, or $0.93 per share, compared to a net loss of $12.2 million, or $0.66 per share, for the first quarter of 2016.

As of March 31, 2017, there were approximately 35.8 million shares of common stock outstanding.

Conference Call
The Company will host a conference call today, May 8, 2017 at 4:30 p.m. Eastern Time / 1:30 p.m. Pacific Time. To participate by telephone, please dial 877-719-9786 (Domestic) or 719-325-4773 (International). The conference ID number is 3868586. A live and archived audio webcast can be accessed through the Investors section of the Company's website at www.achaogen.com. The archived audio webcast will remain available on the Company's website for 30 days following the conference call.

About Achaogen
Achaogen is a late-stage biopharmaceutical company passionately committed to the discovery, development, and commercialization of innovative antibacterials to treat MDR gram-negative infections. Achaogen is developing plazomicin, Achaogen's lead product candidate, for the treatment of serious bacterial infections due to MDR Enterobacteriaceae, including carbapenem-resistant Enterobacteriaceae. Achaogen's plazomicin program is funded in part with Federal funds from the Biomedical Advanced Research and Development Authority (BARDA), Office of the Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, under Contract No. HHSO100201000046C. Plazomicin is the first clinical candidate from Achaogen's gram-negative antibiotic discovery engine. Achaogen has other programs in early and late preclinical stages focused on other MDR gram-negative infections, including an orally-available antibacterial candidate, C-Scape, a combination of an approved beta-lactam and an approved beta-lactamase inhibitor. Achaogen is also pursuing an advanced series of LpxC inhibitor compounds that are active against Pseudomonas aeruginosa, and have been funded in part with Federal funds from the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN272201500009C. All product candidates are investigational only and have not been approved for commercialization. For more information, please visit www.achaogen.com.

Forward-Looking Statements
This press release contains forward-looking statements. All statements other than statements of historical facts contained herein are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, Achaogen's expectations regarding potential regulatory approval of plazomicin, Achaogen's commercial objectives and Achaogen's

pipeline of product candidates. Such forward-looking statements involve known and unknown risks, uncertainties and other important factors that may cause Achaogen's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the preclinical and clinical development process; the risks and uncertainties of the regulatory approval process; the risks and uncertainties of commercialization and gaining market acceptance; the risk when bacteria will evolve resistance to plazomicin; Achaogen's reliance on third-party contract manufacturing organizations to manufacture and supply its product candidates and certain raw materials used in the production thereof; risks and uncertainties related to the acceptance of government funding for certain of Achaogen's programs, including the risk that BARDA or NIAID could terminate Achaogen's contract for the funding of the plazomicin or LpxC inhibitor development programs, respectively; risk of third party claims alleging infringement of patents and proprietary rights or seeking to invalidate Achaogen's patents or proprietary rights; and the risk that Achaogen's proprietary rights may be insufficient to protect its technologies and product candidates. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward- looking statements, as well as risks relating to Achaogen's business in general, see Achaogen's current and future reports filed with the Securities and Exchange Commission, including its Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and its Quarterly Report on Form 10-Q for the quarter ended March 31, 2017. Achaogen does not plan to publicly update or revise any forward-looking statements contained in this press release, whether as a result of any new information, future events, changed circumstances or otherwise.

Source: Achaogen, Inc. (NASDAQ:AKAO)

Achaogen, Inc.
Condensed Consolidated Statements of Operations
(in thousands except share and per share data)
(unaudited)

	Three Months Ended March 31,	
	2017	2016
Contract revenue	$7,463	$5,849
Operating expenses:		
Research and development	18,597	13,893
General and administrative	6,751	3,777
Total operating expenses	25,348	17,670
Loss from operations	(17,885)	(11,821)
Interest expense	(706)	(438)
Change in warrant and derivative liabilities	(14,956)	(12)
Other income, net	288	74
Net loss	$(33,259)	$(12,197)
Basic and diluted net loss per common share	$(0.93)	$(0.66)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	35,725,876	18,398,288

Achaogen, Inc.
Condensed Consolidated Balance Sheets
(in thousands)

	March 31, 2017 (unaudited)	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$37,639	$118,964
Short-term investments	94,405	26,912

Contracts receivable	5,866	12,151
Prepaids and other current assets	9,037	2,189
Restricted cash	127	127
Total current assets	147,074	160,343
Property and equipment, net	8,449	3,261
Restricted cash	250	250
Deposit and other assets	33	71
Total assets	$155,806	$163,925
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$11,585	$5,739
Accrued liabilities	6,490	9,698
Loan payable, current portion	7,292	4,167
Other current liabilities	45	104
Total current liabilities	25,412	19,708
Loan payable, long-term	18,192	21,110
Warrant liability	27,289	13,874
Derivative liability	622	602
Deferred Rent	5,654	1,896
Total liabilities	77,169	57,190
Stockholders' equity	78,637	106,735
Total liabilities and stockholders' equity	$155,806	$163,925

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