ACHAOGEN

November 7, 2016

Achaogen Reports Third Quarter 2016 Financial Results and Announces Acceleration of Expected Timeline for Reporting Top-Line Results from Plazomicin Program

-- Completed Enrollment in Phase 3 Plazomicin Clinical Trials; Expect Results from EPIC and CARE Trials by End of 2016 --

-- Planning Plazomicin NDA Submission in the Second Half of 2017 --

-- Presented First Plazomicin CARE Trial Data in Patients with Carbapenem-Resistant Enterobacteriaceae (CRE) Infections at IDWeek™ 2016 --

-- Conference Call Today at 4:30 p.m. Eastern Time --

SOUTH SAN FRANCISCO, Calif., Nov. 07, 2016 (GLOBE NEWSWIRE) -- Achaogen, Inc. (NASDAQ:AKAO), a clinical-stage biopharmaceutical company developing novel antibacterials addressing multi-drug resistant (MDR) gram-negative infections, today reported financial results for the third quarter of 2016, and announced the acceleration of the expected timeline for reporting results from the Phase 3 clinical trials of its lead product candidate, plazomicin, which is being developed to treat serious bacterial infections due to MDR Enterobacteriaceae, including carbapenem-resistant Enterobacteriaceae (CRE).

"Thanks to the coordinated efforts of our team and participating clinical trial sites, we were successful in completing enrollment of the Phase 3 EPIC trial ahead of schedule, and now expect to announce top-line EPIC and CARE results before the end of 2016," said Kenneth Hillan, M.B. Ch.B., Achaogen's Chief Executive Officer. "Also, at the recent IDWeek conference, we presented the first data from the CARE trial, which highlighted the role of therapeutic drug management in guiding targeted dosing of plazomicin in critically ill patients with antibiotic resistant gram-negative infections."

Recent Highlights and Upcoming Milestones

Plazomicin is currently being evaluated in two Phase 3 clinical trials. The EPIC (**E**valuating **p**lazomicin **i**n **c**UTI) trial is expected to serve as a single registration trial supporting a New Drug Application (NDA) for plazomicin in the United States and a Marketing Authorization Application (MAA) in the European Union. The CARE (**C**ombating **A**ntibiotic **R**esistant **E**nterobacteriaceae) trial is a supportive study in patients with serious bacterial infections due to CRE.

- Completed patient enrollment in both the Phase 3 EPIC registrational trial and ended enrollment in the supportive Phase 3 CARE trial;
- Accelerated the expected timeline for reporting top-line results from both Phase 3 clinical trials of plazomicin. The Company now expects to report top-line results from both the EPIC and CARE clinical trials by the end of 2016 and continues to plan to submit an NDA to the U.S. Food and Drug Administration (FDA) in the second half of 2017;
- Conducted a meeting with the U.K. Medicines & Healthcare products Regulatory Agency (MHRA) and their feedback confirmed that data from the plazomicin development program would support a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA). We plan to submit a MAA for plazomicin in 2018; and
- Presented the first data from the CARE trial at the Infectious Diseases Society of America (IDSA) IDWeek 2016 Annual Meeting outlining the contribution of therapeutic drug management (TDM) in achieving optimal dosing of plazomicin in critically ill patients and showing that plazomicin therapy was well tolerated in the first 10 patients enrolled in Cohort 2 of the CARE trial. Additionally, data against 2,306 clinical isolates collected from 30 U.S. hospitals as part of the 2015 plazomicin surveillance program confirmed the potent *in vitro* activity of plazomicin and that plazomicin was the most active aminoglycoside tested against CRE.

Third Quarter 2016 Financial Results

Unrestricted cash, cash equivalents and short-term investments totaled $61.1 million at September 30, 2016 compared to

$58.7 million at December 31, 2015.

Contract revenue totaled $16.0 million for the third quarter of 2016 compared to $4.5 million for the same period of 2015. 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. 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 expenses were $20.5 million for the third quarter of 2016 compared to $10.0 million reported for the same period in 2015. The increase in research and development expenses during the quarter primarily relates to increased program costs associated with the Phase 3 EPIC trial, higher personnel-related expenses, as well as increased costs related to non-plazomicin research programs.

General and Administrative (G&A) expenses were $4.5 million for the third quarter of 2016 compared to $3.0 million for the same period in 2015. The increase in G&A expenses during the quarter primarily relates to increased activity to support plazomicin development and manufacturing and to prepare for registration and commercialization.

Net other expenses were $1.4 million for the third quarter of 2016 compared to nil for the same period in 2015. 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 third quarter of 2016 was $11.0 million, or $0.41 per share, compared to a net loss of $8.8 million, or $0.48 per share, for the third quarter of 2015.

As of September 30, 2016, there were approximately 27.5 million shares of common stock outstanding.

Conference Call
The Company will host a conference call today, November 7, 2016 at 4:30 p.m. Eastern Time / 1:30 p.m. Pacific Time. To participate by telephone, please dial 877-857-6163 (Domestic) or 719-325-4879 (International). The conference ID number is 6858559. 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.

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 (i) the timing of top-line results from the CARE trial and the EPIC trial, (ii) the timing of the submission of an NDA and an MAA for plazomicin, (iii) whether the CARE trial results will be submitted as supportive data with the plazomicin NDA submission, and (iv) the potential for plazomicin to treat serious bacterial infections due to MDR Enterobacteriaceae. 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; specific risks related to the ongoing Phase 3 EPIC trial and Phase 3 CARE trial; the risk of failure to successfully validate, develop and obtain regulatory clearance or approval for the in vitro diagnostic (IVD) assay for plazomicin; the risks and uncertainties of the regulatory approval process; the risks and uncertainties of commercialization and gaining market acceptance; the risk that bacteria may evolve resistance to plazomicin; risks and uncertainties as to Achaogen's ability to raise additional capital to support the development of plazomicin and its other programs; uncertainties regarding the availability of adequate third-party coverage and reimbursement for newly approved products; Achaogen's reliance on third parties to conduct certain preclinical studies and all of its clinical trials; 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; Achaogen's dependence on its President and Chief Executive Officer; risks and uncertainties related to the acceptance of government funding for certain of Achaogen's programs, including the risk that BARDA could terminate Achaogen's contract for the funding of the plazomicin development program; 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 Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2016. 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.

About Achaogen

Achaogen is a clinical-stage biopharmaceutical company passionately committed to the discovery, development, and commercialization of novel 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, 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 LpxC inhibitors for the treatment of serious bacterial infections including MDR gram-negative bacteria. Achaogen's LpxC inhibitor program has been funded in part with Federal funds from the National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN272201500009C. LpxC inhibitors are the second class of molecules from Achaogen's gram-negative antibiotic discovery engine. For more information, please visit www.achaogen.com.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Contract revenue	$ 16,046	$ 4,476	$ 31,039	$ 21,397
Operating expenses:				
Research and development	20,536	10,000	56,137	27,967
General and administrative	4,460	3,006	12,188	9,119
Total operating expenses	24,996	13,006	68,325	37,086
Loss from operations	(8,950)	(8,530)	(37,286)	(15,689)
Interest expense	(670)	(264)	(1,555)	(264)
Other income (expense), net	(1,418)	32	(2,662)	126
Net loss	$ (11,038)	$ (8,762)	$ (41,503)	$ (15,827)
Basic and diluted net loss per common share	$ (0.41)	$ (0.48)	$ (1.88)	$ (0.88)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	26,789,397	18,150,331	22,046,368	18,073,479

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

	September 30, 2016	December 31, 2015
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 41,802	$ 20,287
Short-term investments	19,287	38,444
Contracts receivable	14,893	5,039
Prepaids and other current assets	3,246	1,719
Restricted cash	127	-
Total current assets	79,355	65,489

Property and equipment, net	1,006	905
Restricted cash	250	127
Deposit and other assets	53	342
Total assets	$ 80,664	$ 66,863
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 7,606	$ 3,537
Accrued liabilities	10,920	4,927
Loan payable, current portion	1,042	-
Other current liabilities	269	225
Total current liabilities	19,837	8,689
Loan payable, long-term	23,975	14,536
Warrant liability	5,422	-
Derivative liability	413	375
Other long-term liabilities	-	104
Total liabilities	49,647	23,704
Stockholders' equity	31,017	43,159
Total liabilities and stockholders' equity	$ 80,664	$ 66,863

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