ACHAOGEN

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Achaogen Provides Clinical Update and First Quarter 2015 Results

SOUTH SAN FRANCISCO, May 11, 2015 (GLOBE NEWSWIRE) -- Achaogen, Inc. (Nasdaq:AKAO), a clinical-stage biopharmaceutical company developing novel antibacterials to treat multi-drug resistant (MDR) gram-negative infections, today reported an update of its Phase 3 plazomicin clinical programs as well as financial results for the quarter ended March 31, 2015.

"Enhancing and advancing the plazomicin development plan following discussions with the FDA was a key accomplishment for the quarter," commented Kenneth Hillan, Chief Executive Officer of Achaogen. "The severity and scale of the global threat of multi-drug resistant bacterial infections continues to grow, and we see the regulatory, legislative, and commercial landscapes evolving in recognition of this unmet medical need. The actions that we have taken position Achaogen to help address these emergent opportunities and make an important contribution to the treatment of patients with limited therapeutic options."

The Company's lead compound, plazomicin, is being developed to treat serious bacterial infections due to Enterobacteriaceae, including carbapenem-resistant Enterobacteriaceae (CRE), and is currently being evaluated in patients with bloodstream infections (BSI) and pneumonia due to CRE in a Phase 3 study titled CARE (Combating Antibiotic Resistant Enterobacteriaceae). In the first quarter, the Company announced an enhanced development plan for plazomicin including the addition of a Phase 3 study in patients with complicated urinary tract infections (cUTI). This additional study significantly expands the market opportunity for plazomicin to include the population of patients with cUTI infections caused by MDR Enterobacteriaceae. In addition, it provides a nearer-term pathway to seek regulatory approval of plazomicin in the United States. Finally, it enhances the probability of technical and regulatory success of the plazomicin program given the success of plazomicin in the prior Phase 2 cUTI study. Based on discussions with the US Food and Drug Administration (FDA), Achaogen expects the Phase 3 cUTI trial to serve as a single pivotal study to support regulatory approval of plazomicin. The trial is expected to commence in Q4 2015 with top-line results and an NDA submission expected in the second half of 2017.

The Phase 3 cUTI trial will be a randomized, double blind, active controlled study in patients with cUTI and acute pyelonephritis. This will be a non-inferiority trial comparing plazomicin to meropenem with a 15% non-inferiority (NI) margin. As such, the trial will have a sample size of approximately 530 patients, which is significantly smaller than prior industry-sponsored Phase 3 cUTI trials. The Company believes that this reflects the FDA's recognition of the unmet need for new antibiotics that treat MDR bacterial infections with high morbidity and mortality. The Company estimates the Phase 3 cUTI trial will necessitate additional Achaogen funding of $45-50 million from 2015 through 2017, which the Company anticipates will be primarily accessed via non-dilutive sources such as government contracts, grants, and debt.

The on-going Phase 3 CARE study will provide data in patients with BSI and pneumonia infections due to CRE, and is expected to enable label expansion following an initial approval based on the cUTI study. The Company has worked with the FDA on a protocol amendment with the goal of improving patient enrollment in the CARE study. The amendment also changes the primary endpoint to include not only mortality, but also other significant disease-related complications, which increases the statistical power of the study and which the Company also believes provides a more sensitive measure of the antibiotic treatment effect. Achaogen's goal is to complete the CARE study, and submit a supplemental NDA during the second half of 2018.

On the corporate front, the Company announced the appointments of Dr. Alan Colowick and Dr. Kent Lieginger to its Board of Directors. Dr. Colowick has held senior managerial positions at large and emerging biotechnology companies. Most recently at Celgene Corporation, he served as President for the Europe, Mid-East, and Africa region from 2012 to 2014 and Senior Vice President Global Medical Affairs from 2010 to 2012. Dr. Lieginger was most recently Senior Vice President, Managed Care and Customer Operations at Genentech, Inc., as well as Director of the Genentech Foundation since 2005. He originally joined Genentech as Vice President, Managed Care and Customer Operations in 2004 and served as a member of Genentech's Commercial Leadership Committee.

Summary Financial Results for the Quarter Ended March 31, 2015

Cash, cash equivalents and short-term investments totaled $61.6 million at March 31, 2015 compared to $63.7 million at December 31, 2014, decreasing as a result of operating losses.

Revenues totaled $4.9 million for the first quarter of 2015 compared to $6.0 million for the comparable quarter in 2014. Achaogen derived all of its revenue from funding provided under U.S. government contracts in connection with the development of product candidates.

Research and development (R&D) expenses totaled $7.9 million for the first quarter of 2015 compared to $6.6 million for the comparable quarter in 2014. Increased R&D costs for the quarter were primarily attributable to increased activities for research programs other than plazomicin and higher personnel related costs.

General and administrative (G&A) expenses totaled $3.2 million for the first quarter of 2015 compared to $2.6 million for the comparable quarter in 2014. Increased costs were primarily attributable to higher personnel-related costs including stock-based compensation expenses and increased costs associated with being a public company.

Net loss totaled $6.2 million for the first quarter of 2015 compared to $3.5 million for the same period of 2014.

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 lung, bloodstream, and urinary tract infections due to Enterobacteriaceae, including CRE. Achaogen's plazomicin program is funded in part with a contract from the Biomedical Advanced Research and Development Authority. Plazomicin is the first clinical candidate from Achaogen's gram-negative antibiotic discovery engine, and Achaogen has other programs in early and late preclinical stages focused on other MDR gram-negative infections. 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 Achaogen's expectations regarding the enrollment and success of its proposed Phase 3 cUTI trial and its ongoing Phase 3 CARE trial, the timing for completion of Achaogen's Phase 3 trials, Achaogen's ability to provide clinical evidence of the overall survival superiority of plazomicin versus colistin for life-threatening bloodstream infections and pneumonia due to CRE, Achaogen's ability to become a leading anti-infective company, and Achaogen's ability to discover, develop and commercialize novel antibacterials to treat MDR gram-negative infections. 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 proposed Phase 3 cUTI trial and the ongoing Phase 3 CARE trial, including the lack of a prior clinical trial in patients with CRE infections and challenges in enrolling an adequate number of patients with rare infections; 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; Achaogen's dependence on ARK Diagnostics, Inc. to develop and manufacture the IVD assay for 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 Chief Executive Officer; risks and uncertainties related to the acceptance of government funding for certain of Achaogen's programs, including the risk that the Biomedical Advanced Research and Development Authority 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 quarterly period ended March 31, 2015 and its Annual Report on Form 10-K for the fiscal year ended December 31, 2014. 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.

Achaogen, Inc.

Condensed Consolidated Statements of Operations

(in thousands except share and per share data)

(Unaudited)

	Three Months Ended March 31,

	2015	2014
Contract revenue	$ 4,880	$ 5,988
Operating expenses:		
Research and development	7,879	6,605
General and administrative	3,231	2,617
Total operating expenses	11,110	9,222
Loss from operations	(6,230)	(3,234)
Interest expense	--	(179)
Other income (expense), net	51	(42)
Net loss	$ (6,179)	$ (3,455)
Basic and diluted net loss per common share	$ (0.34)	$ (1.00)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	17,998,390	3,456,088

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

	March 31 2015 (unaudited)	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 22,933	$ 18,881
Short-term investments	38,713	44,798
Contracts receivable	4,472	5,234
Prepaids and other current assets	605	520
Total current assets	66,723	69,433
Property and equipment, net	648	725
Restricted cash	127	127
Deposit and other assets	47	37
Total assets	$ 67,545	$ 70,322
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,947	$ 2,122
Accrued liabilities	3,254	3,266
Other current liabilities	132	128
Total current liabilities	7,333	5,516
Deferred rent	160	193
Total liabilities	7,493	5,709

Stockholders' equity	60,052	64,613
Total liabilities and stockholders' equity	$ 67,545	$ 70,322

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