Achaogen Reports Second Quarter 2018 Financial Results and Provides Corporate Update

August 6, 2018

-- ZEMDRI (plazomicin), approved in the U.S. for the treatment of adults with complicated urinary tract infections --

-- Launch of ZEMDRI underway; reached more than three quarters of high priority accounts in first two weeks --

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

SOUTH SAN FRANCISCO, Calif., Aug. 06, 2018 (GLOBE NEWSWIRE) -- Achaogen, Inc. (NASDAQ:AKAO), a biopharmaceutical company discovering, developing and commercializing innovative antibacterial agents to address multi-drug resistant (MDR) gram-negative infections, today reported financial results for the second quarter ended June 30, 2018, and provided an update on its commercial and corporate activities.

“With the launch of ZEMDRI, a much needed once-daily antibiotic, we are now able to offer healthcare practitioners a new treatment option for patients with certain serious bacterial infections,” said Blake Wise, Achaogen’s Chief Executive Officer. “We are excited about ZEMDRI’s potential to help patients, and we are pleased with the early interest we are seeing from the infectious disease community.”

Recent Highlights and Upcoming Milestones

- **ZEMDRI Launch**: On July 20, 2018, ZEMDRI was made available for use in the United States. Achaogen has deployed a team of experienced sales and medical professionals to communicate the proper use, efficacy and safety of ZEMDRI, including its once-daily, 30-minute dosing regimen. Greater than 75% of high priority accounts have been engaged in the first two weeks.
- **ZEMDRI U.S. Approval**: On June 25, 2018, the U.S. Food and Drug Administration (FDA) approved ZEMDRI (plazomicin) for adults with complicated urinary tract infections (cUTI), including pyelonephritis, caused by certain Enterobacteriaceae in patients who have limited or no alternative treatment options.
- **ZEMDRI New Technology Add-On Payment (NTAP) Approval**: On August 2, 2018, ZEMDRI received approval from Centers for Medicare & Medicaid Services (CMS) for NTAP, a special designation for new technologies that demonstrate substantial clinical improvement over current treatments. The NTAP payment will provide hospitals with a payment, in addition to the standard-of-care Diagnostic Related Group (DRG) reimbursement, of up to 50% of the cost of ZEMDRI for a period of two to three years, starting on October 1, 2018.
- **European Marketing Authorization Application (MAA)**: Achaogen plans to submit a MAA to the European Medicines Agency for plazomicin in the second half of 2018.

Other Corporate Milestones

- **Strategic Update**: On July 26, 2018, the Company announced a strategic update and corporate restructuring to improve its cost structure for long-term success; a one-time restructuring charge of approximately $6.0 million is expected in the second half of 2018.

Second Quarter 2018 Financial Results

Cash Position: At June 30, 2018, Achaogen had $100.5 million in unrestricted cash, cash equivalents and short-term investments compared to $164.8 million at December 31, 2017.

Revenue: Contract revenue totaled $2.6 million for the second quarter of 2018 compared to $1.3 million for the same period in 2017. The increase in contract revenue during the second quarter was primarily related to Biomedical Advanced Research and Development Authority (BARDA) C-Scape contract revenues. As of June 30, 2018, $8.4 million remains under the BARDA C-Scape contract and up to an additional $6.0 million may be available under BARDA contract options. All Achaogen revenue consisted of U.S. government and Gates Foundation funding for the research and development of product candidates.

Research and Development (R&D): R&D expenses in the second quarter of 2018 were $36.9 million, compared to $22.2 million reported for the same period in 2017. The increase in R&D expenses during the quarter was primarily due to a $7.5 million milestone license fee associated with FDA approval of ZEMDRI, increases in R&D headcount, facility expenses, external expenses related to manufacturing ZEMDRI, and external expenses related to C-Scape and early research programs.

General and Administrative (G&A): G&A expenses in the second quarter of 2018 were $20.5 million, compared to $8.9 million for the same period in 2017. The increase in G&A expenses during the quarter was primarily due to increases in G&A headcount, including the field sales team, facility expenses and expenses related to the pre-commercialization of ZEMDRI.

Change in warrant and derivative liabilities for the second quarter of 2018 was a $4.6 million gain compared to a $4.2 million gain for the same period in 2017. The increase was primarily due to the change in the estimated fair value of the warrant liability which is mainly driven by the change in the Company’s stock price.

Net Loss: Achaogen reported a net loss of $50.0 million for the second quarter of 2018, compared to a net loss of $26.1 million for the same period in

2017. Diluted net loss was $1.20 per share for the second quarter of 2018, compared to diluted net loss of $0.78 per share for the same period in 2017. As of June 30, 2018, there were approximately 45.0 million shares of common stock outstanding.

Conference Call
The Company will host a conference call and webcast today at 4:30 p.m. Eastern Time / 1:30 p.m. Pacific Time. To participate by telephone, please dial 888.254.3590 (Domestic) or 323.994.2093 (International). The conference ID number is 2893252. 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 biopharmaceutical company passionately committed to the discovery, development, and commercialization of innovative antibacterial treatments for MDR gram-negative infections. Achaogen's first commercial product is ZEMDRI, for the treatment of adults with complicated urinary tract infections (cUTI), including pyelonephritis. The Achaogen ZEMDRI program was 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. The Company is currently developing C-Scape, an orally-administered beta-lactam/beta-lactamase inhibitor combination, which is also supported by BARDA. Achaogen is also developing a new aminoglycoside program, which is supported by CARB-X. All product candidates are investigational, have not been determined to be safe or efficacious, and have not been approved for commercialization. For more information, visit the Achaogen website at 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, the potential uses and advantages of ZEMDRI, Achaogen commercial objectives and the Achaogen 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 risks and uncertainties of the regulatory approval process; market size and growth; timing of activities, including launch dates of products; statements about the efficacy, safety and tolerability of ZEMDRI and product candidates; the risks and uncertainties of product sales; the risk of when bacteria will evolve resistance to ZEMDRI and product candidates; Achaogen's reliance on third-party contract manufacturing organizations for manufacture and supply, including sources of certain raw materials; 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 the Achaogen business in general, see Achaogen current and future reports filed with the Securities and Exchange Commission, including its Annual Report on Form 10-K filed on February 27, 2018, and its Quarterly Report on Form 10-Q filed on or about August 6, 2018. 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.

Investor Contact:
Ashley R. Robinson
LifeSci Partners, LLC
arr@lifesciadvisors.com

Media Contact:
Denise T. Powell
Red House Consulting, LLC
dpowell@achaogen.com

Source: Achaogen, Inc.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	**2017**	**2018**	**2017**
Contract revenue	$ 2,562	$ 1,266	$ 4,705	$ 8,729
Operating expenses				
Research and development	36,930	22,199	67,840	40,797
General and administrative	20,478	8,860	35,547	15,609
Total operating expenses	57,408	31,059	103,387	56,406
Loss from operations	(54,846)	(29,793)	(98,682)	(47,677)
Interest expense	(295)	(723)	(900)	(1,430)
Change in warrant and derivative liabilities	4,576	4,225	2,045	(10,731)
Loss on debt extinguishment	—	—	(819)	—
Other income, net	596	221	1,158	510
Net loss	$ (49,969)	$ (26,070)	$ (97,198)	$ (59,328)

Net loss per common share				
Basic	$ (1.11)	$ (0.68)	$ (2.18)	$ (1.61)
Diluted	$ (1.20)	$ (0.78)	$ (2.19)	$ (1.61)
Weighted-average shares used to calculate net loss per common share				
Basic	44,865,861	38,072,763	44,612,623	36,905,802
Diluted	45,691,646	39,092,279	45,425,617	36,905,802

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

	June 30, 2018	December 31, 2017
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 63,291	$ 145,219
Short-term investments	37,244	19,572
Contracts receivable	1,458	1,357
Prepaids and other current assets	9,056	6,367
Restricted cash	5,757	5,891
Total current assets	116,806	178,406
Property and equipment, net	20,611	14,810
Restricted cash	1,206	3,855
Other long-term assets	4,074	—
Total assets	$ 142,697	$ 197,071
Liabilities, contingently redeemable common stock and stockholders' equity		
Current liabilities:		
Accounts payable	$ 6,578	$ 6,862
Accrued liabilities	23,508	15,441
Loan payable, current portion	—	12,500
Deferred revenue	696	2,100
Total current liabilities	30,782	36,903
Loan payable, long-term	24,622	9,457
Warrant liability	7,477	9,774
Derivative liability	938	686
Deferred rent	9,962	8,289
Total liabilities	73,781	65,109
Contingently redeemable common stock	10,000	10,000
Stockholders' equity	58,916	121,962
Total liabilities, contingently redeemable common stock and stockholders' equity	$ 142,697	$ 197,071

Primary Logo

Source: Achaogen, Inc.