

ACHAOPEN

Achaogen Reports Third Quarter 2018 Financial Results and Provides Corporate Update

November 8, 2018

-- Company provides update on ZEMDRI™ commercialization and launch --
-- Conference call today at 8:30 a.m. Eastern Time --

SOUTH SAN FRANCISCO, Calif., Nov. 08, 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 third quarter ended September 30, 2018, and provided an update on its commercial and corporate activities.

"Momentum for ZEMDRI continues to build and we are pleased with the interest we are seeing for the product as a result of ZEMDRI's strong clinical data, differentiated profile, and versatility across inpatient and outpatient treatment settings," said Blake Wise, Achaogen's Chief Executive Officer. "We also advanced other important corporate priorities, including the submission of a Marketing Authorization Application for plazomicin to the European Medicines Agency while streamlining operations and reducing expenses."

Recent Highlights and Upcoming Milestones

- **ZEMDRI Launch Update:** The launch focus continues to be the education of physicians on the clinical profile of ZEMDRI and building the foundation to support product use across the hospital and outpatient settings. The commercial organization continues to build momentum on key leading indicators including: formulary review and approval, orders of antibiotic susceptibility testing materials and customer readiness for therapeutic drug management testing. ZEMDRI revenues for the quarter represent approximately two months of product sales prior to broad formulary approval or the availability of the NTAP supplementary reimbursement, which went into effect on October 1st. During the quarter, ZEMDRI achieved net revenues of \$291,000 and, to date, 60% of use has been in the outpatient setting.
- **European Marketing Authorization Application (MAA):** On October 15, 2018, Achaogen announced the submission of a Marketing Authorization Application (MAA) to the European Medicines Agency for plazomicin seeking approval for the following indications:
 - Complicated urinary tract infections (cUTI), including pyelonephritis
 - Bloodstream infections (BSI) due to certain Enterobacteriaceae and
 - Infections due to Enterobacteriaceae in adult patients with limited treatment options
- **NTAP Designation:** On October 1, 2018, a New Technology Add-on Payment (NTAP) went into effect for ZEMDRI. The NTAP designation is granted for new technologies that demonstrate substantial clinical improvement over current treatments and provides 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 when prescribed to Medicare patients in a hospital setting for a period of two to three years.

Other Corporate Milestones

- **Strategic Review and Restructuring:** On November 5, 2018, the Company announced a review of strategic alternatives to maximize shareholder value and a restructuring to preserve cash resources and reduce total expenses.

Third Quarter 2018 Financial Results

Cash Position: At September 30, 2018, Achaogen had \$58.2 million in unrestricted cash, cash equivalents and short-term investments compared to \$164.8 million at December 31, 2017.

Revenue: Achaogen reported ZEMDRI net product sales of \$0.3 million for the three months ended September 30, 2018. The full commercial launch of ZEMDRI occurred on July 20, 2018 so there were no similar product sales in the same period in 2017. Contract revenue totaled \$1.7 million for the third quarter of 2018 compared to \$0.6 million for the same period in 2017. The increase in contract revenue during the third quarter was primarily related to the BARDA C-Scape contract. As of September 30, 2018, \$7.6 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 contract 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 third quarter of 2018 were \$21.7 million, compared to \$25.3 million reported for the same period in 2017. The decrease in R&D expenses during the quarter was primarily due to a decrease in personnel and facility related costs.

Selling, General and Administrative (SG&A): SG&A expenses in the third quarter of 2018 were \$18.9 million, compared to \$11.8 million for the same period in 2017. The increase in SG&A expenses during the quarter was primarily due to an increase in personnel and facility related costs.

Restructuring Expenses: Restructuring expenses in the third quarter of 2018 were \$7.9 million. There were no restructuring charges for in the same

period in 2017. Restructuring charges include severance and payroll related costs, stock-based compensation costs and net facility exit costs related to our corporate restructuring announced on July 26, 2018.

Warrants and Derivative Liabilities: Change in warrant and derivative liabilities for the third quarter of 2018 was a \$4.9 million gain compared to a \$6.8 million gain for the same period in 2017. The decrease was primarily due to the change in the estimated fair value, which decreased due to the change in our stock price.

Net Loss: Achaogen reported a net loss of \$41.8 million for the third quarter of 2018, compared to a net loss of \$29.9 million for the same period in 2017. Diluted net loss was \$1.02 per share for the third quarter of 2018, compared to diluted net loss of \$0.85 per share for the same period in 2017. As of September 30, 2018, there were approximately 46.0 million shares of common stock outstanding.

Conference Call

The Company will host a conference call and webcast today at 8:30 a.m. Eastern Time / 5:30 a.m. Pacific Time. To participate by telephone, please dial 866-952-8559 (domestic) or 785-424-1745 (international); conference ID: ACHAOPEN. 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, including pyelonephritis. The Achaogen ZEMDRI program was funded in part with federal funds from the Biomedical Advanced Research and Development Authority (BARDA). The Company is currently developing C-Scape, an orally-administered beta-lactam/beta-lactamase inhibitor combination, which is also supported by BARDA. C-Scape is investigational, has not been determined to be safe or efficacious, and has 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 (plazomicin), launch metrics for ZEMDRI, the approval of plazomicin by the EMA, the outcome of Achaogen's strategic review, Achaogen's expectations regarding the timing and impact of its restructuring, Achaogen's strategic and 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 that the strategic review may not be successful, the risks and uncertainties of commercialization and gaining market acceptance, uncertainties inherent in the development process, the risks and uncertainties of the regulatory approval process, the risk when bacteria will evolve resistance to ZEMDRI, Achaogen's reliance on third-party contract manufacturing organizations to manufacture and supply ZEMDRI, its product candidates and certain raw materials used in the production thereof and the risk that Achaogen's proprietary rights may be insufficient to protect ZEMDRI, 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's 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 November 8, 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 and Media Contact:

Martin Forrest
mforrest@achaogen.com
 650-419-3920

Source: Achaogen, Inc.
 © 2018 Achaogen, Inc. All Rights Reserved.

Achaogen, Inc,

Condensed Consolidated Statement of Operations

(in thousands except share and per share data)

(unaudited)

	Three Months Ended		Nine Months Ended	
	September 30, 2018	2017	September 30, 2018	2017
Revenues				
Product revenue, net	\$ 291	\$ —	\$ 291	\$ —
Contract revenue	1,707	577	6,412	9,306
Total revenues	1,998	577	6,703	9,306
Operating expenses				
Cost of sales	11	—	11	—
Research and development	21,732	25,316	89,572	66,113
Selling, general and administrative	18,937	11,805	54,484	27,415
Restructuring charges	7,944	—	7,944	—
Total operating expenses	48,624	37,121	152,011	93,528

Loss from operations	(46,626)	(36,544)	(145,308)	(84,222)
Interest expense	(435)	(740)	(1,335)	(2,170)
Change in warrant and derivative liabilities	4,865		6,773		6,909		(3,957)
Loss on debt extinguishment	—		—		(819)	—	
Other income, net	405		604		1,563		1,114	
Net loss	\$ (41,791)	\$ (29,907)	\$ (138,990)	\$ (89,235)
Net loss per common share								
Basic	\$ (0.92)	\$ (0.71)	\$ (3.10)	\$ (2.31)
Diluted	\$ (1.02)	\$ (0.85)	\$ (3.21)	\$ (2.31)
Weighted-average shares used to calculate net loss per common share								
Basic	45,329,711		42,259,001		44,854,279		38,709,811	
Diluted	45,794,686		43,211,059		45,595,838		38,709,811	

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

	September 30, 2018 (unaudited)	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 55,635	\$ 145,219
Short-term investments	2,589	19,572
Trade and contract receivables, net	1,981	1,357
Inventory	637	—
Prepays and other current assets	6,348	6,367
Restricted cash	328	5,891
Total current assets	67,518	178,406
Property and equipment, net	15,754	14,810
Restricted cash	6,267	3,855
Non-current inventory	1,604	—
Other long-term assets	6,158	—
Total assets	\$ 97,301	\$ 197,071
Liabilities, contingently redeemable common stock and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 10,920	\$ 6,862
Accrued liabilities	14,355	15,441
Loan payable, current portion	—	12,500
Deferred revenue	328	2,100
Derivative liability	950	—
Total current liabilities	26,553	36,903
Loan payable, long-term	24,773	9,457
Warrant liability	2,600	9,774
Derivative liability, long-term	—	686
Deferred rent	8,588	8,289
Total liabilities	62,514	65,109
Commitments and contingencies		
Contingently redeemable common stock	10,000	10,000
Stockholders' equity		
Common stock, \$0.001 par value, 290,000,000 shares authorized at September 30, 2018 and December 31, 2017; 45,967,093 and 42,515,015 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	46	42
Preferred stock, \$0.001 par value, 10,000,000 shares authorized and zero shares issued and outstanding at September 30, 2018 and December 31, 2017	—	—
Additional paid-in-capital	536,569	494,758
Accumulated deficit	(511,828) (372,838
Accumulated other comprehensive loss	—	—
Total stockholders' equity	24,787	121,962
Total liabilities, contingently redeemable common stock and stockholders' equity	\$ 97,301	\$ 197,071

ACHAOPEN

Source: Achaogen, Inc.