# Achaogen Reports Fourth Quarter and Full Year 2018 Financial Results and Provides Corporate Update

March 28, 2019

*-- ZEMDRI's once-daily 30-minute infusion facilitating usage in the outpatient setting --*

*-- Company's recent restructuring aimed at conserving capital to continue assessment of strategic alternatives --*

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

SOUTH SAN FRANCISCO, Calif., March 28, 2019 (GLOBE NEWSWIRE) -- Achaogen, Inc. (Nasdaq: AKAO), a biopharmaceutical company developing and commercializing innovative antibacterial agents to address multi-drug resistant (MDR) gram-negative infections, today reported financial results for the fourth quarter and year ended December 31, 2018, and provided an update on its commercial and corporate activities.

"The team continues to make progress on our launch objectives including gaining formulary access, contracting with physician-owned outpatient infusion centers, and driving ZEMDRI adoption in key markets," said Blake Wise, Achaogen's Chief Executive Officer. "We also remain focused on assessing key opportunities through our review of strategic alternatives."

**Recent Highlights**

- **ZEMDRI® (plazomicin) Launch**: The commercial organization continues to focus on areas of promising initial sales uptake and building a foundation to support adoption of ZEMDRI. Leading indicators such as the number of formulary reviews and approvals, contracts signed with physician-owned outpatient infusion centers, and adoption of antibiotic susceptibility testing and therapeutic drug management continue to trend positively. To date, 75 percent of ZEMDRI use has been in the outpatient setting.

- **Plazomicin Marketing Authorization Application (MAA)**: The Company has received the Day 120 List of Questions from the European Medicines Agency (EMA) as part of the centralized review process of the MAA for plazomicin.

- **C-Scape Oral Antibiotic Program:** The Company's second antibacterial candidate is ready to enter a new Phase 1 human pharmacology study based on in vitro and in vivo experiments with a revised drug product. C-Scape is designed for infections due to ESBL-producing Enterobacteriaceae.

- **Review of Strategic Alternatives and Corporate Restructuring**: The Company remains focused on the review of strategic alternatives and, to support this, recently initiated a further restructuring to reduce quarterly cash operating expenses to $15 million to $17 million per quarter, starting in the second quarter of 2019.

**Fourth Quarter and Year 2018 Financial Results**

**Cash Position**: At December 31, 2018, Achaogen had $31.0 million in unrestricted cash, cash equivalents and short-term investments compared to $164.8 million at December 31, 2017. Achaogen also had $25.5 million in restricted cash as of December 31, 2018 compared to $9.7 million at December 31, 2017. Subsequent to December 31, 2018, Achaogen issued 15,000,000 shares of common stock under a public offering for net proceeds of $13.6 million, after deducting the sales commissions and offering expenses.

**Revenue**: Achaogen reported ZEMDRI net product sales of $0.5 million for the three months-ended December 31, 2018 and $0.8 million for the year ended December 31, 2018. The full commercial launch of ZEMDRI occurred on July 20, 2018; there were no similar product sales in the same period in 2017. Contract revenue totaled $1.5 million for the fourth quarter of 2018 compared to $1.9 million for the same period of 2017. Contract revenue for the year ended December 31, 2018 was $7.9 million compared to $11.2 million for the year ended December 31, 2017. The decrease in contract revenue during the fourth quarter and the year ended December 31, 2018, was primarily due to lower contract revenue from Biomedical Advanced Research and Development Authority (BARDA). As of December 31, 2018, $6.8 million remains on Option 1 of the BARDA C-Scape contract.

**Research and Development (R&D):** R&D expenses in the fourth quarter of 2018 were $13.4 million, compared to $29.5 million reported for the same period in 2017. The decrease in R&D expenses during the quarter was attributable to a decrease in personnel and facility-related costs. For the full year 2018, research and development expenses were $103.0 million, compared to $95.6 million for the full year 2017. The increase in 2018 R&D expenses was primarily attributable to ZEMDRI pre-launch activities in the first half of 2018, C-Scape and early research programs, and license-related milestone payments.

**Selling, General and Administrative (SG&A):** SG&A expenses in the fourth quarter of 2018 were $16.9 million, compared to $14.5 million for the same period in 2017. For the full year 2018, SG&A expenses were $71.4 million, compared to $41.9 million for the full year 2017. The increase in SG&A expenses for the quarter and the year 2018 was primarily attributable to an increase in personnel and facility-related costs, and costs related to the commercialization of ZEMDRI.

**Restructuring Expenses:** Restructuring expenses in the fourth quarter of 2018 were $15.6 million and for the full year of 2018, were $23.5 million. There were no restructuring charges in the same periods in 2017. Restructuring charges include severance and payroll-related costs, stock-based

compensation costs, fixed asset impairment and net facility exit costs related to the Company's corporate restructurings announced in July and November 2018.

**Warrants and Derivative Liabilities:** Change in warrant and derivative liabilities for the fourth quarter of 2018 was a $2.1 million gain compared to a $5.9 million gain for the same period in 2017. The decrease was primarily related to the revaluation of warrants issued in the private placement of common stock and warrants to purchase common stock in June 2016.

**Net Loss**: Achaogen reported a net loss of $47.5 million for the fourth quarter of 2018, compared to a net loss of $36.4 million for the same period in 2017. Basic and diluted net loss was $1.01 per share for the fourth quarter of 2018, compared to diluted net loss of $0.98 per share for the same period of 2017. For the year ended December 31, 2018, net loss was $186.5 million, or diluted net loss of $4.25 per share, compared to a net loss of $125.6 million, or diluted net loss of $3.17 per share, for the year ended December 31, 2017. As of December 31, 2018, there were approximately 48.2 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 800-347-6311 (domestic) or 323-994-2131 (international). The conference ID number is 3056397. 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 ZEMDRI**
ZEMDRI is an aminoglycoside with once-daily dosing that has activity against certain Enterobacteriaceae. Achaogen's EPIC clinical trial successfully evaluated the safety and efficacy of ZEMDRI in adult patients with cUTI, including pyelonephritis. ZEMDRI was engineered to overcome aminoglycoside-modifying enzymes, the most common aminoglycoside-resistance mechanism in Enterobacteriaceae, and has *in vitro* activity against ESBL-producing, aminoglycoside-resistant, and carbapenem-resistant isolates. The Centers for Disease Control and Prevention has characterized ESBL-producing Enterobacteriaceae as a "serious threat" and carbapenem-resistant Enterobacteriaceae (CRE) as "nightmare bacteria," which is an immediate public health threat that requires urgent and aggressive action.

**Indications & Usage**
ZEMDRI (plazomicin) is indicated in patients 18 years of age or older for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis caused by the following susceptible microorganism(s): *Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis*, and *Enterobacter cloacae*.

As only limited clinical safety and efficacy data for ZEMDRI are currently available, reserve ZEMDRI for use in cUTI patients who have limited or no alternative treatment options.

To reduce the development of drug-resistant bacteria and maintain effectiveness of ZEMDRI and other antibacterial drugs, ZEMDRI should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible microorganisms.

**Important Safety Information**

**BOXED WARNINGS: NEPHROTOXICITY, OTOTOXICITY, NEUROMUSCULAR BLOCKADE AND FETAL HARM**

- **Nephrotoxicity has been reported with ZEMDRI. The risk of nephrotoxicity is greater in patients with impaired renal function, the elderly, and in those receiving concomitant nephrotoxic medications. Assess creatinine clearance in all patients prior to initiating therapy and daily during therapy. Therapeutic Drug Monitoring (TDM) is recommended for complicated urinary tract infection (cUTI) patients with CLcr less than 90 mL/min to avoid potentially toxic levels.**
- **Ototoxicity, manifested as hearing loss, tinnitus, and/or vertigo, has been reported with ZEMDRI. Symptoms of aminoglycoside-associated ototoxicity may be irreversible and may not become evident until after completion of therapy. Aminoglycoside-associated ototoxicity has been observed primarily in patients with a family history of hearing loss, patients with renal impairment, and in patients receiving higher doses and/or longer durations of therapy than recommended.**
- **Aminoglycosides have been associated with neuromuscular blockade. During therapy with ZEMDRI, monitor for adverse reactions associated with neuromuscular blockade, particularly in high-risk patients, such as patients with underlying neuromuscular disorders (including myasthenia gravis) or in patients concomitantly receiving neuromuscular blocking agents.**
- **Aminoglycosides, including ZEMDRI, can cause fetal harm when administered to a pregnant woman.**

**Contraindications:** ZEMDRI is contraindicated in patients with known hypersensitivity to any aminoglycoside.

**Additional Warnings and Precautions**

- **Nephrotoxicity:** Reported with the use of ZEMDRI. Most serum creatinine increases were ≤ 1 mg/dL above baseline and reversible. Assess CLcr in all patients prior to initiating therapy and daily during therapy with ZEMDRI, particularly in those at increased risk of nephrotoxicity, such as those with renal impairment, the elderly and those receiving concomitant potentially nephrotoxic medications. In the setting of worsening renal function, the benefit of continuing ZEMDRI should be assessed. Adjust the initial dosage regimen in cUTI patients with CLcr ≥ 15 mL/min and < 60 mL/min. For subsequent

doses, TDM is recommended for patients with CLcr ≥ 15 mL/min and < 90 mL/min.

- **Ototoxicity:** Reported with ZEMDRI (manifested as hearing loss, tinnitus, and/or vertigo). Symptoms of aminoglycoside-associated ototoxicity may be irreversible and may not become evident until after completion of therapy. Aminoglycoside-associated ototoxicity has been observed primarily in patients with a family history of hearing loss (excluding age-related hearing loss), patients with renal impairment, and in patients receiving higher doses and/or for longer periods than recommended. The benefit-risk of ZEMDRI therapy should be considered in these patients.

- **Neuromuscular Blockade:** Aminoglycosides have been associated with exacerbation of muscle weakness in patients with underlying neuromuscular disorders, or delay in recovery of neuromuscular function in patients receiving concomitant neuromuscular blocking agents. During therapy with ZEMDRI, monitor for adverse reactions associated with neuromuscular blockade, particularly in high-risk patients, such as patients with underlying neuromuscular disorders (including myasthenia gravis) or those patients concomitantly receiving neuromuscular blocking agents.

- **Fetal Harm:** Aminoglycosides, including ZEMDRI, can cause fetal harm when administered to a pregnant woman. Patients who use ZEMDRI during pregnancy, or become pregnant while taking ZEMDRI should be apprised of the potential hazard to the fetus.

- **Hypersensitivity Reactions:** Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients receiving aminoglycoside antibacterial drugs. Before therapy with ZEMDRI is instituted, careful inquiry about previous hypersensitivity reactions to other aminoglycosides should be made. Discontinue ZEMDRI if an allergic reaction occurs.

- **Clostridium difficile-Associated Diarrhea (CDAD):** Reported for nearly all systemic antibacterial drugs and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial drugs alters the normal flora of the colon and may permit overgrowth of C. difficile. Careful medical history is necessary. If CDAD is suspected or confirmed, antibacterial drugs not directed against C. difficile may need to be discontinued.

- **Development of Drug-Resistant Bacteria:** Prescribing ZEMDRI in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Please click here to see the full Prescribing Information, including BOXED WARNINGS, for additional Important Safety Information.

**You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Achaogen at (833) AKAO-402.**

**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, Achaogen expectations regarding Achaogen's commercial operations and financial position. 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 timing of activities; the risk of not obtaining sufficient funding for the desired activities of Achaogen; statements about the efficacy, safety and tolerability of ZEMDRI; the risks and uncertainties of product sales; the review and approval of plazomicin by the EMA; the risk of Achaogen continuing as a going concern; Achaogen's reliance on third-party contract manufacturing organizations for manufacture and supply, including sources of certain raw materials; 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 expected to be filed on April 1, 2019, and its most recent 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.

Source: Achaogen, Inc.



**Achaogen, Inc.**

**Consolidated Statements of Operations**
**(in thousands except share and per share data)**

| | Three Months Ended December 31, | | Twelve Months Ended December 31, | |
|---|---|---|---|---|
| | **2018** | **2017** | **2018** | **2017** |
| Revenues | | | | |
| Product revenue, net | $ 492 | $ — | $ 783 | $ — |
| Contract revenue | 1,533 | 1,869 | 7,945 | 11,175 |
| Total revenues | 2,025 | 1,869 | 8,728 | 11,175 |
| Operating expenses | | | | |
| Cost of sales | 20 | - | 31 | - |
| Research and development | 13,386 | 29,485 | 102,959 | 95,598 |
| Selling, general and administrative | 16,901 | 14,488 | 71,385 | 41,903 |
| Restructuring charges | 15,574 | — | 23,518 | — |
| Total operating expenses | 45,881 | 43,973 | 197,893 | 137,501 |
| Loss from operations | (43,856) | (42,103) | (189,165) | (126,326) |
| Interest expense | (778) | (685) | (2,112) | (2,855) |
| Change in warrant and derivative liabilities | 2,143 | 5,885 | 9,053 | 1,928 |
| Loss on debt extinguishment | — | — | (819) | — |
| Loss on redeemable common stock settlement | (5,179) | — | (5,179) | — |
| Other income, net | 147 | 522 | 1,710 | 1,635 |
| Net loss | $ (47,523) | $ (36,382) | $ (186,512) | $ (125,618) |
| Net loss per common share: | | | | |
| Basic | $ (1.01) | $ (0.86) | $ (4.11) | $ (3.17) |
| Diluted | $ (1.01) | $ (0.98) | $ (4.25) | $ (3.17) |
| Weighted-average shares used to compute net loss per common share | | | | |
| Basic | 46,957,396 | 42,422,592 | 45,384,380 | 39,645,635 |
| Diluted | 46,957,396 | 43,257,602 | 46,027,950 | 39,645,635 |

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

| | December 31, 2018 | December 31, 2017 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 30,956 | $ 145,219 |
| Short-term investments | — | 19,572 |
| Trade and contract receivables, net | 1,861 | 1,357 |
| Inventory | 515 | — |
| Assets held for sale | 1,509 | — |
| Prepaids and other current assets | 1,412 | 6,367 |
| Restricted cash | 25,000 | 5,891 |
| Total current assets | 61,253 | 178,406 |
| Property and equipment, net | 2,471 | 14,810 |
| Non-current restricted cash | 530 | 3,855 |
| Non-current inventory | 8,846 | — |
| Other long-term assets | 9,190 | — |
| Total assets | $ 82,290 | $ 197,071 |
| **Liabilities, contingently redeemable common stock and stockholders' equity (deficit)** | | |
| Current liabilities: | | |
| Accounts payable | $ 12,472 | $ 6,862 |
| Accrued liabilities | 15,232 | 15,441 |
| Loan payable, current portion | 49,784 | 12,500 |
| Deferred revenue | — | 2,100 |
| Derivative liability | 963 | — |
| Total current liabilities | 78,451 | 36,903 |
| Loan payable, long-term | — | 9,457 |

| | | |
|---|---|---|
| Warrant liability | 444 | 9,774 |
| Derivative liability, long-term | — | 686 |
| Deferred rent | 9,682 | 8,289 |
| Total liabilities | 88,577 | 65,109 |
| Contingently redeemable common stock | — | 10,000 |
| Stockholders' equity (deficit) | (6,287) | 121,962 |
| Total liabilities, contingently redeemable common stock and stockholders' equity (deficit) | $ 82,290 | $ 197,071 |

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Source: Achaogen, Inc.