

# ACHAAGEN INC

## **FORM 8-K** (Current report filing)

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Address	7000 SHORELINE COURT SUITE 371 SOUTH SAN FRANCISCO, CA, 94080
Telephone	650-800-3636
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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT  
Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): May 4, 2018**

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**ACHAOGEN, INC.**  
(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-36323**  
(Commission  
File Number)

**68-0533693**  
(IRS Employer  
Identification Number)

**1 Tower Place, Suite 300**  
**South San Francisco, CA 94080**  
(Address of principal executive offices, including Zip Code)

**Registrant's telephone number, including area code: (650) 800-3636**

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging Growth Company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financing accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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**Item 2.02 Results of Operations and Financial Condition.**

On May 4, 2018, the Company issued a press release announcing its financial results for the first quarter ended March 31, 2018. The press release is attached hereto as Exhibit 99.1.

The information in this Item 2.02 of this Form 8-K and the Exhibit 99.1 attached hereto shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the “Securities Act”), or incorporated by reference in any filing of the Company under the Securities Act or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	<a href="#">Press Release dated May 4, 2018.</a>

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ACHAOGEN, INC.

Date: May 4, 2018

By: /s/ Gary Loeb  
Gary Loeb  
General Counsel



## NEWS RELEASE

### Achaogen Reports First Quarter 2018 Financial Results and Provides Corporate Update

— FDA Advisory Committee voted in favor of plazomicin for treatment of adults with complicated urinary tract infections —

— Conference call today at 8:30 a.m. Eastern Time —

SOUTH SAN FRANCISCO, Calif., May 4, 2018 – Achaogen, Inc. (NASDAQ: AKAO), a late-stage biopharmaceutical company discovering and developing innovative antibacterials addressing multi-drug resistant (MDR) gram-negative infections, today reported financial results for the first quarter ended March 31, 2018, and provided an update on its corporate and clinical development activities.

“With a unanimous vote earlier this week in favor of plazomicin for the treatment of patients with complicated urinary tract infections (cUTI), we are laser-focused on the potential launch of our first drug,” said Blake Wise, Achaogen’s Chief Executive Officer. “We remain committed to our vision of developing new treatment options for patients with serious bacterial infections.”

#### Recent Highlights and Upcoming Milestones

- **Plazomicin Advisory Committee Meeting** : The U.S. Food and Drug Administration (FDA) Advisory Committee voted in favor of plazomicin for the treatment of cUTI, including pyelonephritis (15 to 0), and not in favor for the treatment of bloodstream infections (BSI) in adults with limited or no treatment options (4 to 11).
- **Plazomicin PDUFA Date** : The plazomicin Prescription Drug User Fee Act (PDUFA) target action date is June 25, 2018. Should plazomicin receive approval by the target action date, the Company expects to launch plazomicin soon thereafter. Plazomicin commercial launch plans for the U.S. are in the advanced stages of development.
- **Plazomicin Marketing Authorization Application (MAA)** : Achaogen plans to submit a MAA to the European Medicines Agency in the second half of 2018.
- **C-Scape Program** : Based on pharmacokinetic/pharmacodynamic (PK/PD) modeling, the Company now plans to conduct an additional Phase 1 clinical pharmacology trial. The additional Phase 1 trial is intended to optimize the likelihood of clinical and commercial success and will delay the initiation of a pivotal Phase 3 clinical trial beyond 2018. The FDA awarded Qualified Infectious Disease Product (QIDP) status to C-Scape for the treatment of cUTI in 2017.

#### Other Corporate Milestones

- **CARB-X Research Funding** : The Company recently entered into an award agreement with CARB-X. Under the agreement, Achaogen was awarded up to \$2.4 million, with the possibility of up to \$9.6 million more. The collaboration will focus on the development of a next-generation broad-spectrum aminoglycoside antibiotic capable of overcoming clinically-relevant resistance mechanisms and potentially treating highly-resistant gram-negative pathogens.

**First Quarter 2018 Financial Results**

**Cash Position** : At March 31, 2018, Achaogen had \$144.0 million in unrestricted cash, cash equivalents and short-term investments compared to \$164.8 million at December 31, 2017. In February, Achaogen refinanced a \$25.0 million secured debt line it had with Solar Capital with a new \$50.0 million secured debt line with Silicon Valley Bank, and has drawn \$25.0 million under the Silicon Valley Bank agreement to repay the Solar Capital facility. As previously disclosed, the Company issued 2,144,454 shares of common stock under its at-the-market equity facility for net proceeds, in the first quarter, of \$24.0 million.

**Revenue** : Contract revenue totaled \$2.1 million for the first quarter of 2018 compared to \$7.5 million for the same period of 2017. The decrease in contract revenue during the first quarter was primarily due to lower Biomedical Advanced Research and Development Authority (BARDA) contract revenues. As of March 31, 2018, \$9.6 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 revenue consists 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 first quarter of 2018 were \$30.9 million, compared to \$18.6 million reported for the same period in 2017. The increase in R&D expenses during the quarter was primarily due to increases in headcount, facility expenses, external expenses related to plazomicin product supply, C-Scape and early research program expenses.

**General and Administrative (G&A)**: G&A expenses in the first quarter of 2018 were \$15.1 million, compared to \$6.8 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, facility expenses and expenses related to the potential commercialization of plazomicin.

Change in warrant and derivative liabilities for the first quarter of 2018 was a \$2.5 million loss compared to a \$15.0 million loss for the same period in 2017. The decrease was primarily due to the change in the estimated fair value of the warrant liability which is mainly driven by the change in our stock price.

**Net Loss** : Achaogen reported a net loss of \$47.2 million for the first quarter of 2018, compared to a net loss of \$33.3 million for the same period in 2017. Diluted net loss was \$1.06 per share for the first quarter of 2018, compared to diluted net loss of \$0.93 per share for the same period of 2017. As of March 31, 2018, there were approximately 44.8 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 800 239 9838 (Domestic) or 323 794 2551 (International). The conference ID number is 6288003. A live and archived audio webcast can be accessed through the Investors section of the Company's website at [www.achaogen.com](http://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 late-stage biopharmaceutical company passionately committed to the discovery, development, and commercialization of innovative antibacterial treatments for MDR gram-negative infections. Achaogen is developing plazomicin, its lead product candidate, for the treatment of serious bacterial infections due to MDR Enterobacteriaceae, including carbapenem-resistant Enterobacteriaceae. The Food and Drug Administration has granted plazomicin Breakthrough Therapy designation for the treatment of bloodstream infections caused by certain Enterobacteriaceae in patients who have limited or no alternative treatment options. Achaogen's plazomicin program has been 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's second product candidate C-Scape, an orally-administered beta-lactam/beta-lactamase inhibitor combination, is funded in part with Federal funds from BARDA, Office of the Assistant Secretary for Preparedness and Response, Office of the Secretary, U.S. Department of Health and Human Services, under Contract No. HHSO100201700021C. Achaogen has other programs in early and late preclinical stages focused on other MDR gram-negative infections and additional disease areas. All product candidates, including plazomicin, are investigational only and have not been approved for commercialization. For more information, please visit [www.achaogen.com](http://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's expectations regarding potential regulatory approval of plazomicin and other product candidates, Achaogen's plan to launch plazomicin soon after receiving FDA approval, Achaogen's plan to submit a MAA to the European Medicines Agency in 2018 and Achaogen's 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 uncertainties inherent in the preclinical and clinical development process; the risks and uncertainties of the regulatory approval process; the risks and uncertainties of product sales and effectiveness; 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 Achaogen's 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 for the quarter ended March 31, 2018 expected to be filed the week of May 7, 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.

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

	Three Months Ended	
	March 31,	
	2018	2017
Contract revenue	\$ 2,143	\$ 7,463
Operating expenses		
Research and development	30,911	18,597
General and administrative	15,069	6,751
Total operating expenses	45,980	25,348
Loss from operations	(43,837)	(17,885)
Interest expense	(604)	(706)
Change in warrant and derivative liabilities	(2,531)	(14,956)
Loss on debt extinguishment	(819)	—
Other income, net	562	288
Net loss	\$ (47,229)	\$ (33,259)
Basic	\$ (1.06)	\$ (0.93)
Basic	44,356,570	35,725,876

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

	<b>March 31,</b>	<b>December 31,</b>
	<b>2018</b>	<b>2017</b>
	(unaudited)	<u>          </u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 94,898	\$ 145,219
Short-term investments	49,100	19,572
Contracts receivable	1,789	1,357
Prepays and other current assets	8,944	6,367
Restricted cash	6,998	5,891
Total current assets	<u>161,729</u>	<u>178,406</u>
Property and equipment, net	17,228	14,810
Restricted cash	1,320	3,855
Other long-term assets	2,828	—
Total assets	<u>\$ 183,105</u>	<u>\$ 197,071</u>
<b>Liabilities, contingently redeemable common stock and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 6,870	\$ 6,862
Accrued liabilities	14,657	15,441
Loan payable, current portion	—	12,500
Deferred revenue	1,545	2,100
Total current liabilities	<u>23,072</u>	<u>36,903</u>
Loan payable, long-term	24,472	9,457
Warrant liability	12,161	9,774
Derivative liability	830	686
Deferred rent	9,477	8,289
Total liabilities	<u>70,012</u>	<u>65,109</u>
Commitments and contingencies		
Contingently redeemable common stock	10,000	10,000
Stockholders' equity	<u>103,093</u>	<u>121,962</u>
Total liabilities, contingently redeemable common stock and stockholders' equity	<u>\$ 183,105</u>	<u>\$ 197,071</u>