ACHAOGEN INC

FORM 8-K
(Current report filing)

Filed 02/27/18 for the Period Ending 02/27/18

Address	7000 SHORELINE COURT SUITE 371 SOUTH SAN FRANCISCO, CA, 94080
Telephone	650-800-3636
CIK	0001301501
Symbol	AKAO
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event reported): February 27, 2018

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

Delaware	001-36323	68-0533693
(State or other jurisdiction of incorporation)	(Commission File Number)	(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

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. ☐

Item 2.02. Results of Operations and Financial Condition.

On February 27, 2018, the Company issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2017. 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.

Exhibit Number	Description
99.1	Press Release dated February 27, 2018.

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: February 27, 2018

By: /s/ Tobin Schilke
Tobin Schilke
Chief Financial Officer

ACHAOGEN

NEWS RELEASE

Achaogen Reports Fourth Quarter and Full Year 2017 Financial Results and Provides Corporate Update

-- Plazomicin New Drug Application (NDA) accepted by U.S. Food and Drug Administration (FDA); June 25, 2018 set as PDUFA action date --

-- Orally-administered antibacterial candidate C-Scape achieved positive top-line results in Phase 1 --

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

SOUTH SAN FRANCISCO, Calif., February 27, 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 fourth quarter and year ended December 31, 2017, and provided an update on its corporate and clinical development activities.

"We gained considerable momentum in 2017 that culminated with FDA acceptance of our plazomicin NDA submission and positive results from our first clinical trial of C-Scape, our second antibacterial product candidate," said Blake Wise, Achaogen's Chief Executive Officer. "There remains a significant unmet need for the treatment of serious bacterial infections due to MDR Enterobacteriaceae, including carbapenem-resistant Enterobacteriaceae (CRE), and we look forward to the potential approval of plazomicin this year and the opportunity to make plazomicin available to hospitals and patients in need."

Recent Highlights and Upcoming Milestones

- **Plazomicin Approval Application (United States)** : The FDA accepted for review the Company's New Drug Application (NDA) for plazomicin for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis, and bloodstream infections (BSI) due to certain Enterobacteriaceae in patients who have limited or no alternative treatment options. Plazomicin previously received FDA Breakthrough Therapy Designation for the treatment of bloodstream infections (BSI) caused by certain Enterobacteriaceae in patients who have limited or no alternative treatment options.
- **Plazomicin PDUFA Date** : The plazomicin NDA has Priority Review and the 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. The FDA recently upgraded the status of the plazomicin fill manufacturer, the Pfizer CentreOne McPherson facility, to Voluntary Action Indicated (VAI), clearing a regulatory path for approval of plazomicin out of this facility. The FDA is currently planning to hold an advisory committee meeting to discuss the application.
- **Plazomicin Approval Application (European Union)** : Achaogen currently plans to submit a Marketing Authorization Application to the European Medicines Agency in the second half of 2018.
- **C-Scape Phase 1 Clinical Trial** : Positive top-line results from a Phase 1 clinical trial of C-Scape demonstrated that the drug was well tolerated across all doses studied in the clinical trial, with no drug-drug interaction between ceftibuten and clavulanate when dosed in combination.

- **C-Scape Components** : C-Scape is an oral combination of ceftibuten, an approved third generation cephalosporin, and clavulanate, an approved beta-lactamase inhibitor. C-Scape was awarded Qualified Infectious Disease Product (QIDP) status by the FDA for the treatment of cUTI.
- **C-Scape Phase 3 Program** : Achaogen plans to meet with regulatory agencies in the first half of 2018 to seek agreement on the details of the C-Scape development plan that would include initiating, in 2018, a pivotal trial in patients with cUTI.

Other Corporate Milestones

- Refinanced an existing $25.0 million debt line with Solar Capital with a new $50.0 million secured debt line with Silicon Valley Bank, which has an interest-only period until at least February 2020.
- Thermo Fisher Scientific received an Acceptance Review Notification for its 510(k) submission for its assay enabling therapeutic drug management (TDM) of plazomicin. The notification from the FDA confirms that the submission contains all of the necessary information needed to proceed with the substantive review.

Fourth Quarter and Year 2017 Financial Results

Cash Position : At December 31, 2017, Achaogen had $164.8 million in unrestricted cash, cash equivalents and short-term investments compared to $145.9 million at December 31, 2016. Subsequent to December 31, 2017, 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. The Company also issued 2,144,454 shares of common stock under its at-the-market equity facility for net proceeds of $24.0 million.

Revenue : Contract revenue totaled $1.9 million for the fourth quarter of 2017 compared to $10.7 million for the same period of 2016. Contract revenue for the year ended December 31, 2017 was $11.2 million compared to $41.8 million for the year ended December 31, 2016. The decrease in contract revenue during the fourth quarter and 2017 was primarily due to lower Biomedical Advanced Research and Development Authority (BARDA) contract revenues. As of December 31, 2017, $11.0 million remains on Option 1 of the BARDA C-Scape contract. Achaogen derived all of its revenue from funding provided under Gates Foundation and U.S. government contracts in connection with the research and development of product candidates.

Research and Development (R&D): R&D expenses in the fourth quarter of 2017 were $29.5 million, compared to $17.9 million reported for the same period in 2016. The increase in R&D expenses during the quarter was attributable to increased personnel and facility-related costs as net headcount increased, external expenses related to plazomicin product supply and pre-launch activities, C-Scape and early research programs. For the full year 2017, research and development expenses were $95.6 million, compared to $74.0 million for the full year 2016. The increase in 2017 R&D expenses was primarily attributable to increased personnel and facility related costs, increased expenses related to C-Scape and early research programs, offset by decreases related to the plazomicin program.

General and Administrative (G&A): G&A expenses in the fourth quarter of 2017 were $14.5 million, compared to $4.9 million for the same period in 2016. For the full year 2017, G&A expenses were $41.9 million, compared to $17.1 million for the full year 2016. The increase in G&A expenses for the quarter

and the year 2017 was primarily attributable to an increase in personnel and facility-related costs, and in costs related to preparation for the commercialization of plazomicin.

Change in warrant and derivative liabilities for the fourth quarter of 2017 was a $5.9 million gain compared to a $17.0 million loss for the same period in 2016. The increase was primarily related to non-cash gain for 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 $36.4 million for the fourth quarter of 2017, compared to a net loss of $29.7 million for the same period in 2016. Diluted net loss was $0.98 per share for the fourth quarter of 2017, compared to diluted net loss of $1.04 per share for the same period of 2016. For the year ended December 31, 2017, net loss was $125.6 million, or $3.17 per share, compared to a net loss of $71.2 million, or $3.00 per share, for the year ended December 31, 2016. As of December 31, 2017, there were approximately 42.5 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 800-281-7973 (Domestic) or 323-794-2093 (International). The conference ID number is 3750290. 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 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.

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 commercial objectives 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 uncertainties of having an NDA accepted by the FDA, 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. 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. (NASDAQ: AKAO)

##

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

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

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2017	2016	2017	2016
Contract revenue	$ 1,869	$ 10,734	$ 11,175	$ 41,773
Operating expenses				
Research and development	29,485	17,862	95,598	73,999
General and administrative	14,488	4,934	41,903	17,122
Total operating expenses	43,973	22,796	137,501	91,121
Loss from operations	(42,104)	(12,062)	(126,326)	(49,348)
Interest expense	(685)	(765)	(2,855)	(2,320)
Change in warrant and derivative liabilities	5,885	(16,978)	1,928	(19,859)
Other income, net	522	81	1,635	300
Net loss	$ (36,382)	$ (29,724)	$ (125,618)	$ (71,227)
Net loss per common share:				
Basic	$ (0.86)	$ (1.04)	$ (3.17)	$ (3.00)
Diluted	$ (0.98)	$ (1.04)	$ (3.17)	$ (3.00)
Weighted-average shares used to compute net loss per common share				
Basic	42,422,592	28,653,045	39,645,635	23,707,063
Diluted	43,257,602	28,653,045	39,645,635	23,707,063

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

	December 31, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 145,219	$ 118,964
Short-term investments	19,572	26,912
Contracts receivable	1,357	12,151
Prepaids and other current assets	6,367	2,189
Restricted cash	5,891	127
Total current assets	178,406	160,343
Property and equipment, net	14,810	3,261
Restricted cash	3,855	250
Deposit and other assets	—	71
Total assets	$ 197,071	$ 163,925
Liabilities, contingently redeemable common stock and stockholders' equity		
Current liabilities:		
Accounts payable	$ 6,862	$ 5,739
Accrued liabilities	15,441	9,698
Loan payable, current portion	12,500	4,167
Deferred revenue	2,100	—
Other current liabilities	—	104
Total current liabilities	36,903	19,708
Loan payable, long-term	9,457	21,110
Warrant liability	9,774	13,874
Derivative liability	686	602
Deferred rent	8,289	1,896
Total liabilities	65,109	57,190
Commitments and contingencies		
Contingently redeemable common stock	10,000	—
Stockholders' equity	121,962	106,735
Total liabilities, contingently redeemable common stock and stockholders' equity	$ 197,071	$ 163,925