ACHAOGEN INC

FORM 8-K
(Current report filing)

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Industry	Biotechnology & Medical Research
Sector	Healthcare
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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): January 30, 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. ☐

It em 8.01 Other Events.

On January 30, 2018, Achaogen, Inc. issued the press release attached as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated January 30, 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: January 30, 2018

By: /s/ Gary Loeb
Gary Loeb
General Counsel

Exhibit 99.1

ACHAOGEN

Achaogen Announces Upgraded Status for Plazomicin Fill Manufacturer

-- McPherson, Kansas facility compliance status amended to Voluntary Action Indicated (VAI) --

-- VAI status provides a clear regulatory path for potential approval of plazomicin out of McPherson facility --

SOUTH SAN FRANCISCO, Calif., January 30, 2018 – Achaogen, Inc. (NASDAQ: AKAO), a late-stage biopharmaceutical company developing innovative antibacterials addressing multi-drug resistant (MDR) gram-negative infections, today announced that the Food and Drug Administration (FDA) has classified the outcome of its fourth quarter 2017 reinspection of Pfizer's McPherson facility as Voluntary Action Indicated (VAI). The Company's New Drug Application (NDA) for plazomicin is currently under regulatory review, and the change to VAI status provides a clear regulatory path for approval for plazomicin out of the McPherson facility based on plazomicin's PDUFA date of June 25, 2018.

"The upgraded VAI designation received by Pfizer's McPherson facility is a positive outcome," said Blake Wise, Achaogen's Chief Executive Officer. "Our PDUFA date is five months away and, with additional clarity around our manufacturing efforts, we look forward to the potential marketing approval and launch of plazomicin."

The Company's NDA for plazomicin is 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. The FDA has set a target action date under the Prescription Drug User Fee Act (PDUFA) of June 25, 2018.

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. 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 is C-Scape, an orally-administered beta-lactam/beta-lactamase inhibitor combination that is funded in part with federal funds from BARDA. 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, 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 achievemen ts 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 commercialization and gaining market acceptance; the risk when bacteria will evolve resistance to plazomicin; Achaogen's reliance on third-party contract manufacturing or ganizations to manufacture and supply its product candidates and certain raw materials used in the production thereof; risk of third party claims alleging infringement of patents and proprietary rights or seeking to invalidate Achaogen's patents or proprie tary 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 March 14, 2017 and its Quarterly Report on Form 10-Q for the quarter ended September 30, 2017. 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, chan ged circumstances or otherwise.

Source: Achaogen, Inc.

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