Achaogen Inc
Form 8-K
September 01, 2016

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): September 1, 2016

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)

7000 Shoreline Court, Suite 371
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))

Item 8.01 Other Events.

On September 1, 2016, Achaogen, Inc. ("Achaogen") announced that it has completed patient enrollment in its Phase 3 EPIC (Evaluating plazomicin in cUTI) trial of plazomicin and closed enrollment in its Phase 3 CARE (Combating Antibiotic Resistant Enterobacteriaceae) trial of plazomicin. Achaogen also announced that it expects to report top-line results from its Phase 3 EPIC trial and Phase 3 CARE trial early in the first quarter of 2017 and continues to plan to submit a New Drug Application ("NDA") for plazomicin to the U.S. Food and Drug Administration ("FDA") in the second half of 2017.

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 the success of Achaogen's ongoing Phase 3 EPIC trial and Phase 3 CARE trial and the timing for completion of Achaogen's Phase 3 trials and submission of an NDA to the FDA. 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; specific risks related to the ongoing Phase 3 EPIC trial and Phase 3 CARE trial, including the lack of a prior clinical trial in patients with infections caused by carbapenem-resistant Enterobacteriaceae; the risk of failure to successfully validate, develop and obtain regulatory clearance or approval for the in vitro diagnostic assay for plazomicin; the risks and uncertainties of the regulatory approval process; the risks and uncertainties of commercialization and gaining market acceptance; the risk that bacteria may evolve resistance to plazomicin; risks and uncertainties as to Achaogen's ability to raise additional capital to support the development of plazomicin and its other programs; Achaogen's reliance on third parties to conduct certain preclinical studies and all of its clinical trials; and Achaogen's reliance on third-party contract manufacturing organizations to manufacture and supply its product candidates and certain raw materials used in the production thereof. 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2016 and its Annual Report on Form 10-K for the fiscal year ended December 31, 2015.

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.

Date: September 1, 2016 ACHAOGEN, INC.

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