Achaogen Inc
Form 8-K
December 12, 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): December 12, 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 December 12, 2016, Achaogen, Inc. ("Achaogen") announced that its lead product candidate, plazomicin, met the objective of non-inferiority compared to meropenem for the U.S. Food and Drug Administration ("FDA") and achieved superiority for the European Medicines Agency ("EMA") primary efficacy endpoints in the Phase 3 EPIC registration trial in patients with complicated urinary tract infections ("cUTI") and acute pyelonephritis ("AP"). In addition, in the Phase 3 CARE trial in patients with serious infections due to carbapenem-resistant Enterobacteriaceae ("CRE"), a lower rate of mortality or serious disease-related complications was observed for plazomicin compared with colistin therapy, one of the few remaining antibiotics for treatment of infections due to CRE.

Achaogen plans to submit a New Drug Application ("NDA"), which will include EPIC and CARE data, to the FDA in the second half of 2017. Achaogen also plans to submit a Marketing Authorization Application ("MAA") to the EMA in 2018. In addition, Achaogen plans to publicly present detailed results from both the EPIC and CARE trials in 2017.

In the EPIC trial, plazomicin successfully met the objective of non-inferiority compared to meropenem for the FDA-specified primary efficacy endpoints, and achieved superiority for the EMA-specified primary efficacy endpoints.

Results for FDA pre-specified composite endpoint of clinical cure and microbiological eradication in the microbiological modified intent-to-treat ("mMITT") population were as follows:

- Day 5: 88.0% plazomicin vs. 91.4% meropenem (difference -3.4%, 95% CI: -10.0, 3.1%), indicating statistical non-inferiority
- Test-of-Cure: 81.7% plazomicin vs. 70.1% meropenem (difference 11.6%, 95% CI: 2.7, 20.3%), indicating statistical superiority

Results for EMA-specified endpoints of microbiological eradication at the test-of-cure visit were as follows:

- mMITT: 87.4% plazomicin vs. 72.1% meropenem (difference 15.4%, 95% CI: 7.5, 23.2%), indicating statistical superiority
- ME: 90.5% plazomicin vs. 76.6% meropenem (difference 13.9%, 95% CI: 6.3, 21.7%), indicating statistical superiority

Phase 3 EPIC Trial in Patients with cUTI: Summary of FDA and EMA Primary Efficacy Endpoints
(* indicates statistical superiority)

	Plazomicin n/N (%)	Meropenem n/N (%)	Difference (%)[a] (95% CI)
Composite endpoint at Day 5, mMITT (FDA)	168/191 (88.0%)	180/197 (91.4%)	-3.4% (-10.0, 3.1%)
Composite endpoint at TOC, mMITT (FDA)	156/191 (81.7%)	138/197 (70.1%)	11.6% (2.7, 20.3%)*
Microbiological eradication at TOC, mMITT (EMA)	167/191 (87.4%)	142/197 (72.1%)	15.4% (7.5, 23.2%)*
Microbiological eradication at TOC, ME (EMA)	162/179 (90.5%)	134/175 (76.6%)	13.9% (6.3, 21.7%)*

CI: confidence interval; ME: microbiologically evaluable; mMITT: microbiological modified intent-to-treat; TOC: test-of-cure; [a] Difference = plazomicin minus meropenem

Plazomicin was well tolerated with no new safety concerns identified in the EPIC trial. Total treatment emergent adverse events ("TEAEs") related to renal function were reported in 3.6% and 1.3% of patients in the plazomicin and meropenem groups, respectively. TEAEs related to cochlear or vestibular function were reported in a single patient in each of the plazomicin and meropenem treatment groups. Both events were considered mild and resolved completely.

In the Phase 3 CARE trial in patients with serious infections due to CRE a lower rate of mortality or serious disease-related complications was observed for plazomicin compared with colistin therapy.

Results from the CARE trial were as follows:

- Day 28 all-cause mortality or significant disease related complications (primary endpoint); 23.5% plazomicin vs. 50.0% colistin (difference 26.5%, 90% CI: -0.7, 51.2%)
- Day 28 all-cause mortality; 11.8% plazomicin vs. 40.0% colistin (difference 28.2%, 90% CI: 0.7, 52.5%)

Phase 3 CARE Trial in Patients with BSI or HABP/VABP due to CRE
(Cohort 1 mMITT population)

	Plazomicin n/N (%)	Colistin n/N (%)	Difference[a] (90% CI)	Relative Reduction
Day 28 all-cause mortality or significant disease-related complications	4/17 (23.5%)	10/20 (50.0%)	26.5% (-0.7, 51.2%)	53.0%
Day 28 all-cause mortality	2/17 (11.8%)	8/20 (40.0%)	28.2% (0.7, 52.5%)	70.5%

[a] Difference = colistin minus plazomicin

The safety profile of plazomicin was favorable to that of colistin in critically ill patients in the CARE trial. Study drug-related TEAEs related to renal function were reported in 16.7% and 38.1% of patients in the plazomicin and colistin groups, respectively. No TEAEs related to cochlear or vestibular function were reported in either group.

About the EPIC Trial

EPIC (Evaluating plazomicin in cUTI) was a multinational, randomized, controlled, double-blind clinical trial in adult patients with cUTI and AP. The trial enrolled 609 patients who were randomized 1:1 to receive plazomicin 15 mg/kg as a once daily 30-minute intravenous ("IV") infusion or meropenem 1.0 gram every 8 hours as a 30 minute IV infusion. After a minimum of 4 days of IV therapy, patients who met protocol-defined criteria for improvement were allowed to step-down to oral levofloxacin to complete a total of 7 to 10 days of therapy (IV plus oral).

About the CARE Trial

CARE (Combating Antibiotic Resistant Enterobacteriaceae) was a multinational, open label, Phase 3 clinical trial evaluating the efficacy and safety of plazomicin in patients with serious bacterial infections due to CRE. The study included two cohorts of patients. Cohort 1 (N=39) was a randomized, comparator-controlled cohort to compare plazomicin with colistin (either in combination with meropenem or tigecycline) for the treatment of bloodstream infection ("BSI"), hospital acquired bacterial pneumonia ("HABP") or ventilator associated bacterial pneumonia ("VABP") due to CRE. Cohort 1 enrolled 30 patients with BSI and 9 patients with HABP/VABP. Cohort 2 (N=30) was a single-arm expanded access cohort to evaluate plazomicin-based therapy in patients with BSI, HABP/VABP or cUTI due to CRE who were not eligible for enrollment in Cohort 1.

The primary analysis for Cohort 1 was conducted in the mMITT population (patients with confirmed CRE infection) and was defined as all-cause mortality at Day 28 or significant disease related complications. Due to limitations of the small sample size, no formal statistical hypothesis testing was performed, but a two-sided 90% exact confidence interval is provided to describe the degree of variability around the observed differences.

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 plan to submit an NDA to the FDA in the second half of 2017, Achaogen's plans to submit an MAA to the EMA in 2018, Achaogen's expectations regarding whether the full CARE trial results will be submitted as supportive data with the plazomicin NDA submission and Achaogen's plan to publicly present detailed results from both the EPIC and CARE trials in 2017. 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 risk of failure to successfully validate, develop and obtain regulatory clearance or approval for an in vitro diagnostic (IVD) 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 and potential commercialization of plazomicin and its other programs; uncertainties regarding the availability of adequate third-party coverage and reimbursement for newly approved products; Achaogen's reliance on third parties to conduct certain preclinical studies and all of its clinical trials; 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; Achaogen's dependence on its President and Chief Executive Officer; risks and uncertainties related to the acceptance of government funding for certain of Achaogen's programs, including the risk that the Biomedical Advanced Research and Development Authority (BARDA) could terminate Achaogen's contract for the funding of the plazomicin development program; 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 Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2016 , and its Annual Report on Form 10-K for the fiscal year ended December 31, 2015. Achaogen does not plan to publicly update or revise any forward-looking.

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: December 12, 2016 ACHAOGEN, INC.

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