ACHAOGEN 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

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): August 3, 2017

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 2.02. Results of Operations and Financial Condition.

On August 3, 2017, the Company issued a press release announcing its financial results for the three and six months ended June 30, 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 August 3, 2017.

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: August 3, 2017

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

Exhibit 99.1

ACHAOGEN

PRESS RELEASE

Achaogen Reports Second Quarter 2017 Financial Results and Provides Corporate Update

-- Plazomicin granted Breakthrough Therapy designation --

-- C-Scape Phase 1 study underway to evaluate orally-administered antibacterial candidate for infections due to ESBL-producing Enterobacteriaceae --

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

SOUTH SAN FRANCISCO, Calif., August 3, 2017 – 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 second quarter 2017, and provided an update on its corporate and clinical development activities.

"We made excellent progress this quarter including being granted FDA Breakthrough Therapy designation for plazomicin, securing more than a dozen plazomicin presentations at ASM Microbe, and dosing the first patient in our C-Scape clinical development program," said Kenneth Hillan, M.B. Ch.B., Achaogen's Chief Executive Officer. "Our planned plazomicin NDA application is our top priority and we remain on track to file the NDA in 2017."

Recent Highlights and Upcoming Milestones

Plazomicin has successfully completed two Phase 3 clinical trials and the Company continues to plan to submit a New Drug Application (NDA) to the Food and Drug Administration (FDA) in the second half of 2017 and to submit a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in 2018. The EPIC (**E** valuating **P** lazomicin **I** n **c** UTI) trial is expected to serve as a single registration trial supporting an NDA for plazomicin in the United States and an MAA in the European Union. The second study, the Phase 3 CARE (**C** ombating **A** ntibiotic **R** esistant **E** nterobacteriaceae) trial was a resistant pathogen trial designed to evaluate the efficacy and safety of plazomicin in patients with serious bacterial infections due to carbapenem-resistant Enterobacteriaceae (CRE) and provides additional data supporting the NDA and plazomicin therapy in these patients.

- The U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation for plazomicin for the treatment of bloodstream infections (BSI) caused by certain Enterobacteriaceae in patients who have limited or no alternative treatment options.
- Presented data at ASM Microbe that highlighted the potential of plazomicin against MDR gram-negative bacteria in clinical and non-clinical settings. Thirteen abstracts were accepted, including oral presentations of the Phase 3 EPIC and CARE clinical trials:
  - New analyses of the Phase 3 EPIC trial highlighted the favorable efficacy of plazomicin in the subgroup of patients with bacteremia, and a statistically higher rate of microbiological eradication and a lower infection relapse rate in plazomicin-treated patients compared to meropenem at the late follow-up visit (LFU) time point; and
  - Further analyses of the Phase 3 CARE trial highlighted that plazomicin was associated with a higher microbiological response rate compared to colistin and, in terms of key safety outcomes, was associated with a lower incidence and magnitude of serum creatinine increases compared to colistin.

C-Scape is an orally-available antibacterial candidate that is a combination of an approved beta-lactam and an approved beta-lactamase inhibitor, with the potential to treat patients with cUTI due to MDR pathogens such as extended spectrum beta-lactamase (ESBL)-pr oducing *Escherichia coli* and *Klebsiella pneumoniae* .

- Treated the first human subject with C-Scape in a Phase 1 clinical pharmacology, dosing and safety study; if successful, plan to proceed to pivotal Phase 3 cUTI trial initiation in the first half of 2018.

Other Corporate Highlights

- Completed an underwritten public offering of 5,750,000 shares of its common stock at a price of $22.50 per share, which included the exercise in full of the underwriters' option to purchase an additional 750,000 shares of common stock. Net proceeds were approximately $121.2 million after deducting discounts, commissions and offering expenses.
- Appointed Dr. Karen Bernstein, Co-Founder and Chairman of BioCentury Inc., to its Board of Directors.
- Awarded a grant by Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X), an international antimicrobial consortium to accelerate global antibacterial innovation and research, to support the development of LpxC; the grant consists of $3.2 million over 12 months, and potentially up to a total award of $11.4 million after that period upon achievement of certain milestones.

Second Quarter 2017 Financial Results

Cash, cash equivalents and short-term investments totaled $230.3 million, and restricted cash totaled $12.6 million at June 30, 2017.

Contract revenue totaled $1.3 million for the second quarter of 2017 compared to $9.1 million for the same period of 2016. The decrease in contract revenue during the quarter was primarily due to full utilization of BARDA funding available under the current contract.

Research and development (R&D) expenses were $22.2 million for the second quarter of 2017 compared to $21.7 million reported for the same period in 2016. The increase in R&D expenses during the quarter was attributable to increase in personnel and facility related costs as net headcount increase in our research and development organization, increase of external expenses related to C-Scape clinical program, offset by decreases related to the plazomicin clinical and other research programs.

General and Administrative (G&A) expenses were $8.9 million for the second quarter of 2017 compared to $4.0 million for the same period in 2016. The increase in G&A expenses during the quarter was primarily attributable to increase in personnel and facility related costs, and in costs related to preparation for the commercialization of plazomicin.

Net loss for the second quarter of 2017 was $26.1 million compared to net loss of $18.3 million for the second quarter of 2016. Diluted net loss per share were $0.78 in the second quarter of 2017, compared to diluted net loss per share of $0.87 in the second quarter of 2016.

As of June 30, 2017, there were approximately 42.2 million shares of common stock outstanding.

Conference Call

The Company will host a conference call today, August 3, 2017 at 4:30 p.m. Eastern Time / 1:30 p.m. Pacific Time. To participate by telephone, please dial 888-262-8942 (Domestic) or 719-325-2491 (International). The conference ID number is 5142531. 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 antibacterials to treat MDR gram-negative infections. Achaogen is developing plazomicin, Achaogen's lead product candidate, for the treatment of serious bacterial infections due to MDR Enterobacteriaceae, including carbapenem-resistant Enterobacteriaceae. Achaogen's plazomicin program is 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. Plazomicin is the first clinical candidate from Achaogen's gram-negative antibiotic discovery engine. Achaogen has other programs in early and late preclinical stages focused on other MDR gram-negative infections, including an orally-available antibacterial candidate, C-Scape, a combination of an approved beta-lactam and an approved beta-lactamase inhibitor. Achaogen is also pursuing an advanced series of LpxC inhibitor compounds that are active against Pseudomonas aeruginosa, and have been funded in part with Federal funds from the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN272201500009C. The LpxC inhibitor program will be funded in part with funds from Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X). All product candidates 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 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 commercialization and gaining market acceptance; the risk when bacteria will evolve resistance to plazomicin; 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; risks and uncertainties related to government or grant funding for certain of Achaogen's programs, including the risk that such funding could terminate and impact development programs; 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 for the fiscal year ended December 31, 2016 and its Quarterly Report on

Form 10-Q for the quarter ended March 31, 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, changed circumsta nces or otherwise.

Source: Achaogen, Inc. (NASDAQ: AKAO)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Contract revenue	$1,266	$9,144	$8,729	$14,993
Operating expenses:				
Research and development	22,199	21,708	40,797	35,601
General and administrative	8,860	3,951	15,609	7,728
Total operating expenses	31,059	25,659	56,406	43,329
Loss from operations	(29,793)	(16,515)	(47,677)	(28,336)
Interest expense	(723)	(447)	(1,430)	(885)
Change in warrant and derivative liabilities	4,225	(1,382)	(10,731)	(1,382)
Other income, net	221	76	510	138
Net loss	$(26,070)	$(18,268)	$(59,328)	$(30,465)
Net loss per common share:				
Basic	$(0.68)	$(0.87)	$(1.61)	$(1.55)
Diluted	$(0.78)	$(0.87)	$(1.61)	$(1.55)
Weighted-average common shares used to calculate net loss per common share				
Basic	38,072,763	20,899,297	36,905,802	19,648,792
Diluted	39,092,279	20,899,297	36,905,802	19,648,792

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

	June 30, 2017 (unaudited)	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$143,999	$118,964
Short-term investments	86,295	26,912
Contracts receivable	1,117	12,151
Prepaids and other current assets	7,810	2,189
Restricted cash	8,991	127
Total current assets	248,212	160,343
Property and equipment, net	11,415	3,261
Restricted cash	3,575	250
Deposit and other assets	-	71
Total assets	$263,202	$163,925
Liabilities, contingently redeemable common stock and stockholders' equity		
Current liabilities:		
Accounts payable	$7,850	$5,739
Accrued liabilities	8,385	9,698
Loan payable, current portion	10,417	4,167
Deferred revenue	2,968	-
Other current liabilities	28	104
Total current liabilities	29,648	19,708
Loan payable, long-term	15,280	21,110
Warrant liability	23,043	13,874
Derivative liability	642	602
Deferred Rent	6,076	1,896
Total liabilities	74,689	57,190
Contingently redeemable common stock	10,000	-
Stockholders' equity	178,513	106,735
Total liabilities, contingently redeemable common stock and stockholders' equity	$263,202	$163,925

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