

ACADIA PHARMACEUTICALS INC

Form 8-K

March 06, 2019

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): March 5, 2019

ACADIA Pharmaceuticals Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of

incorporation or organization)

000-50768
(Commission

File Number)

061376651
(IRS Employer

Identification No.)

3611 Valley Centre Drive, Suite 300

92130

San Diego, California
(Address of principal executive offices) **(Zip Code)**
Registrant's telephone number, including area code: (858) 558-2871

N/A

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. of Form 8-K):

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 financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events.

On March 5, 2019, ACADIA Pharmaceuticals Inc. (the Company) submitted an update to the data available through the Centers for Medicare and Medicaid Services (CMS) Open Payments database to reclassify certain categorization information regarding general payments provided to physicians. The update will be reflected in the publicly available data posted on OpenPaymentsData.CMS.gov on June 30, 2019. The individual transaction amounts, as well as the aggregate figures previously submitted for 2016 and 2017, were and remain accurate, subject to minor changes throughout the year to reflect information that became available after the reporting deadline, such as changes made directly by healthcare professionals in the Open Payments system.

For the Company, the mean general payment amount was approximately \$380 for physicians in the United States in 2016, out of approximately 1,580 physicians reported, and approximately \$1,225 for physicians in the United States in 2017, out of approximately 7,060 physicians reported.

The Company was subject to the reporting requirements for only a portion of 2016 because its first Medicare/Medicaid-covered product, NUPLAZID® (pimavanserin), was approved in April 2016 and launched in June 2016. The Company's update relates to categorization details, and the tables below summarize those details as updated. These amounts may be subject to minor changes post-submission as a result of routine, ongoing validation by CMS within the Open Payments system.

2016 (for the period from November 22 to December 31)

| Nature of Payment | Total Payments | Total Amount | Total Amount (%) |
|---|---------------------------|-------------------------|---------------------------------|
| Consulting Fee | 16 | \$ 18,031.75 | 3.0 |
| Comp. for services other than consulting, including speaker/faculty fees for non-CME programs | 166 | \$ 431,615.00 | 71.7 |
| Honoraria | 1 | \$ 2,300.00 | 0.4 |
| Education | 13 | \$ 210.29 | 0.0 |
| Travel and Lodging | 262 | \$ 84,572.16 | 14.0 |
| Food and Beverage | 1,927 | \$ 62,614.37 | 10.4 |
| Grant | 2 | \$ 2,700.00 | 0.4 |

2017 (full year)

| Nature of Payment | Total Payments | Total Amount | Total Amount (%) |
|---|---------------------------|-------------------------|---------------------------------|
| Consulting Fee | 154 | \$ 494,278.65 | 5.7 |
| Comp. for services other than consulting, including speaker/faculty fees for non-CME programs | 2,325 | \$ 6,667,785.00 | 77.1 |
| Education | 11 | \$ 276.40 | 0.0 |
| Travel and Lodging | 2,876 | \$ 740,151.98 | 8.6 |
| Food and Beverage | 23,629 | \$ 616,336.74 | 7.1 |
| Grant | 6 | \$ 132,855.00 | 1.5 |

NUPLAZID is the first and only FDA-approved treatment for hallucinations and delusions associated with Parkinson's disease psychosis. During 2017, the first full year of launch activities, the Company focused on educating physicians and other healthcare professionals regarding Parkinson's disease psychosis, the importance of identifying symptoms, and the benefits, risks, and appropriate use of NUPLAZID. These early launch activities play a critical role in advancing patient care and ensuring that NUPLAZID is used in a safe and effective manner. In calendar year 2018, the second full year of marketing NUPLAZID, the Company's aggregate general payments to physicians decreased to approximately \$4,700,000. The Company will submit payment information for 2018 to the Open Payments system by the annual deadline of March 31, 2019.

The Company has policies, procedures, training, and compliance monitoring in place to foster compliance with laws, regulations, and the Voluntary Compliance Program Guidance for Pharmaceutical Manufacturers developed by the Office of Inspector General (OIG) of the Department of Health and Human Services, including the provisions covering relationships with physicians, as well as with the provisions of the PhRMA Code governing speaker programs.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: March 5, 2019

ACADIA Pharmaceuticals Inc.

By: /s/ Austin D. Kim

Name: Austin D. Kim

Title: Executive Vice President, General Counsel &
Secretary