
**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): February 26, 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
San Diego, California
(Address of principal executive offices)

92130
(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 2.02 Results of Operations and Financial Condition.

On February 26, 2019, ACADIA Pharmaceuticals Inc. issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2019. A copy of this press release is furnished herewith as Exhibit 99.1. Pursuant to the rules and regulations of the Securities and Exchange Commission, such exhibit and the information set forth therein and in this Item 2.02 have been furnished and 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 liability under that section nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing regardless of any general incorporation language.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated February 26, 2019.

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.

ACADIA Pharmaceuticals Inc.

Dated: February 26, 2019

By: /s/ Austin D. Kim
Austin D. Kim
Executive Vice President, General Counsel &
Secretary

**ACADIA Pharmaceuticals Reports
Fourth Quarter and Full Year 2018 Financial Results**

- Fourth Quarter 2018 Net Sales Grew to \$59.6 Million, a 37% Increase Over 4Q17

- Full Year 2018 Net Sales Grew to \$223.8 Million, a 79% Increase Over Full Year 2017

- Late Stage Pipeline Progressing with Five Clinical Programs Ongoing or Commencing in 2019

- 2019 Guidance: Net Sales \$275 Million to \$300 Million

SAN DIEGO, CA, February 26, 2019 – ACADIA Pharmaceuticals Inc. (Nasdaq: ACAD), a biopharmaceutical company focused on the development and commercialization of innovative medicines to address unmet medical needs in central nervous system (CNS) disorders, today announced its financial results for the fourth quarter and full year ended December 31, 2018.

“Our team successfully executed on all three of our strategic pillars in 2018. We grew NUPLAZID in Parkinson’s disease psychosis, leveraged pimavanserin in additional large market CNS indications with positive data from our Phase 2 CLARITY study in adjunctive treatment of major depressive disorder, and expanded our CNS pipeline with the acquisition of the North American rights for trofinetide,” said Steve Davis, ACADIA’s Chief Executive Officer. “2019 will be a pivotal year for ACADIA. We are on track to announce top-line data from our Phase 3 pimavanserin study in adjunctive treatment of schizophrenia mid-year. In addition, we expect to realize strong NUPLAZID revenue and volume growth, while advancing our late-stage pipeline.”

Recent Highlights

- Announced positive top-line results from the Phase 2 CLARITY trial of pimavanserin for adjunctive treatment in patients with major depressive disorder (MDD) in October 2018.
 - Conducted an End-of-Phase 2 meeting with the FDA confirming the development plans for pimavanserin as a potential adjunctive therapy for MDD in February 2019.
 - The Company plans to initiate two Phase 3 trials for pimavanserin as an adjunctive treatment for MDD in the first half of 2019.
 - The Company has confirmed its Phase 3 study design for trofinetide in Rett syndrome with the FDA and plans to initiate this trial in the second half of 2019.
 - Completed a public offering with net proceeds of approximately \$298.5 million in November 2018.
 - Appointed Serge Stankovic, M.D., M.S.P.H., as President in November 2018.
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Financial Results

Revenue

Net sales of NUPLAZID® (pimavanserin) were \$59.6 million for the fourth quarter of 2018, an increase of 37% as compared to \$43.6 million reported for the fourth quarter of 2017. For the year ended December 31, 2018 and 2017, ACADIA reported net product sales of \$223.8 million and \$124.9 million, respectively, an increase of 79%.

Research and Development

Research and development expenses for the fourth quarter of 2018 were \$48.2 million, compared to \$43.2 million for the same period of 2017. For the year ended December 31, 2018 and 2017, research and development expenses were \$187.2 million and \$149.2 million, respectively. The increase in research and development expenses during the 2018 periods as compared to 2017 was primarily due to additional clinical study costs incurred by the Company as it continues to invest in additional pipeline programs for pimavanserin as well as an upfront payment of \$10.0 million to Neuren Pharmaceuticals for trofinetide in the third quarter of 2018.

Selling, General and Administrative

Selling, general and administrative expenses for the fourth quarter of 2018 were \$74.3 million, compared to \$66.7 million for the same period of 2017. For the year ended December 31, 2018 and 2017, selling, general and administrative expenses were \$265.8 million and \$255.1 million, respectively. The increase in selling, general and administrative expenses during the 2018 periods as compared to 2017 was primarily due to an increase in advertising expenses related to our direct-to-consumer advertising campaign.

Net Loss

For the fourth quarter of 2018, ACADIA reported a net loss of \$65.5 million, or \$0.50 per common share, compared to a net loss of \$68.9 million, or \$0.55 per common share, for the same period in 2017. The net losses in the fourth quarter of 2018 and 2017 included \$20.4 million and \$22.0 million, respectively, of non-cash stock-based compensation expense. For the year ended December 31, 2018, ACADIA reported a net loss of \$245.2 million, or \$1.94 per common share, compared to a net loss of \$289.4 million, or \$2.36 per common share, for the same period in 2017. The net losses for the year ended December 31, 2018 and 2017 included \$81.6 million and \$75.5 million, respectively, of non-cash stock-based compensation expense.

Cash and Investments

At December 31, 2018, ACADIA's cash, cash equivalents, and investment securities totaled \$473.5 million, compared to \$341.3 million at December 31, 2017.

2019 Financial Guidance

- NUPLAZID net sales are expected to be between \$275 million and \$300 million.
 - GAAP R&D is expected to be between \$250 million and \$265 million. The increase compared to 2018 reflects the planned progression of five late-stage clinical programs in 2019.
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- GAAP SG&A is expected to be between \$280 million and \$295 million.
- Non-cash stock-based compensation expense is expected to be between \$80 million and \$90 million.

Conference Call and Webcast Information

ACADIA management will review its fourth quarter and full year 2018 financial results and operations via conference call and webcast today at 5:00 p.m. Eastern Time. The conference call may be accessed by dialing 855-638-4820 for participants in the U.S. or Canada and 443-877-4067 for international callers (reference passcode 3094204). A telephone replay of the conference call may be accessed through March 12, 2019 by dialing 855-859-2056 for callers in the U.S. or Canada and 404-537-3406 for international callers (reference passcode 3094204). The conference call also will be webcast live on ACADIA's website, [www.acadia-pharm.com](#), under the investors section and will be archived there through March 26, 2019.

About NUPLAZID® (pimavanserin)

NUPLAZID is the first and only FDA-approved treatment for hallucinations and delusions associated with Parkinson's disease psychosis. NUPLAZID is a non-dopaminergic, selective serotonin inverse agonist (SSIA) preferentially targeting 5-HT_{2A} receptors that are thought to play an important role in Parkinson's disease psychosis. NUPLAZID is an oral medicine taken once a day with a recommended dose of 34 mg. ACADIA discovered and developed this new chemical entity and holds worldwide rights to develop and commercialize NUPLAZID.

About ACADIA Pharmaceuticals

ACADIA is a biopharmaceutical company focused on the development and commercialization of innovative medicines to address unmet medical needs in central nervous system disorders. ACADIA has developed and is commercializing the first and only medicine approved for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis. In addition, ACADIA has ongoing clinical development efforts in additional areas with significant unmet need, including dementia-related psychosis, schizophrenia inadequate response, schizophrenia-negative symptoms, major depressive disorder, and Rett syndrome. This press release and further information about ACADIA can be found at: www.acadia-pharm.com.

Forward-Looking Statements

Statements in this press release that are not strictly historical in nature are forward-looking statements. These statements include, but are not limited to, statements related to: the potential opportunity for future growth in sales of NUPLAZID, including through sales of new dosages and forms; the timing of ongoing and future clinical studies for pimavanserin; the development and commercialization of trofinetide; and guidance for full-year 2019 NUPLAZID net sales and certain expense line items. These statements are only predictions based on current information and expectations and involve a number of risks and uncertainties. Actual events or results may differ materially from those projected in any of such statements due to various factors, including the uncertainty of future commercial sales and related items that would impact net sales during 2019, the risks and uncertainties inherent in drug discovery, development, approval and commercialization, and the fact that past results of clinical trials may not be indicative of future trial results. For a discussion of these and other factors, please refer to ACADIA's annual report on Form 10-K for the year ended December 31, 2017 as well as ACADIA's subsequent filings

with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All forward-looking statements are qualified in their entirety by this cautionary statement and ACADIA undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof, except as required by law.

ACADIA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)
(Unaudited)

	<u>Three Months Ended December 31,</u>		<u>Years Ended December 31,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
Revenues				
Product sales, net	\$ 59,571	\$ 43,562	\$ 223,807	\$ 124,901
Total revenues	59,571	43,562	223,807	124,901
Operating expenses				
Cost of product sales, license fees and royalties (1)	4,392	3,703	18,330	13,060
Research and development (1)	48,183	43,179	187,163	149,189
Selling, general and administrative (1)	74,271	66,689	265,758	255,062
Total operating expenses	126,846	113,571	471,251	417,311
Loss from operations	(67,275)	(70,009)	(247,444)	(292,410)
Interest income, net	1,670	1,107	5,348	4,126
Other expense	127	—	(1,840)	—
Loss before income taxes	(65,478)	(68,902)	(243,936)	(288,284)
Income tax expense	14	(31)	1,256	1,119
Net loss	\$ (65,492)	\$ (68,871)	\$ (245,192)	\$ (289,403)
Net loss per common share, basic and diluted	\$ (0.50)	\$ (0.55)	\$ (1.94)	\$ (2.36)
Weighted average common shares outstanding, basic and diluted	131,627	124,117	126,583	122,600

(1) Includes the following share-based compensation expense

Cost of product sales, license fees and royalties	\$ 838	\$ 719	\$ 3,863	\$ 3,690
Research and development	\$ 8,421	\$ 7,887	\$ 32,038	\$ 26,485
Selling, general and administrative	\$ 11,142	\$ 13,413	\$ 45,663	\$ 45,357

ACADIA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	December 31, 2018	December 31, 2017
	(unaudited)	
Assets		
Cash, cash equivalents and investment securities	\$ 473,520	\$ 341,342
Accounts receivable, net	26,090	17,343
Interest and other receivables	1,699	1,087
Inventory	4,070	5,248
Prepaid expenses	20,727	8,457
Total current assets	526,106	373,477
Property and equipment, net	3,309	2,662
Intangible assets, net	4,062	5,538
Restricted cash	4,826	2,475
Other assets	1,899	354
Total assets	\$ 540,202	\$ 384,506
Liabilities and stockholders' equity		
Accounts payable	\$ 3,167	\$ 8,786
Accrued liabilities	56,398	40,244
Total current liabilities	59,565	49,030
Long-term liabilities	1,558	191
Total liabilities	61,123	49,221
Total stockholders' equity	479,079	335,285
Total liabilities and stockholders' equity	\$ 540,202	\$ 384,506

Important Safety Information and Indication for NUPLAZID (pimavanserin)

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

- **Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death.**
- **NUPLAZID is not approved for the treatment of patients with dementia-related psychosis unrelated to the hallucinations and delusions associated with Parkinson's disease psychosis.**

Contraindication: NUPLAZID is contraindicated in patients with a history of a hypersensitivity reaction to pimavanserin or any of its components. Rash, urticaria, and reactions consistent with angioedema (e.g., tongue swelling, circumoral edema, throat tightness, and dyspnea) have been reported.

QT Interval Prolongation: NUPLAZID prolongs the QT interval. The use of NUPLAZID should be avoided in patients with known QT prolongation or in combination with other drugs known to prolong QT interval including Class 1A antiarrhythmics or Class 3 antiarrhythmics, certain antipsychotic medications, and certain antibiotics. NUPLAZID should also be avoided in patients with a history of cardiac arrhythmias, as well as other circumstances that may increase the risk of the occurrence of torsade de pointes and/or sudden death, including symptomatic bradycardia, hypokalemia or hypomagnesemia, and presence of congenital prolongation of the QT interval.

Adverse Reactions: The most common adverse reactions ($\geq 2\%$ for NUPLAZID and greater than placebo) were peripheral edema (7% vs 2%), nausea (7% vs 4%), confusional state (6% vs 3%), hallucination (5% vs 3%), constipation (4% vs 3%), and gait disturbance (2% vs $<1\%$).

Drug Interactions: Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole) increases NUPLAZID exposure. Reduce NUPLAZID dose to 10 mg taken orally as one tablet once daily. Coadministration with strong CYP3A4 inducers may reduce NUPLAZID exposure. Monitor patients for reduced efficacy and an increase in NUPLAZID dosage may be needed.

Pediatric Use: Safety and efficacy have not been established in pediatric patients.

Dosage and Administration: Recommended dose: 34 mg taken orally once daily, without titration.

Indication: NUPLAZID is an atypical antipsychotic indicated for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088. You can also call ACADIA Pharmaceuticals Inc. at 1-844-4ACADIA (1-844-422-2342).

NUPLAZID is available as 34 mg capsules and 10 mg tablets.

Please see the full Prescribing Information including **Boxed WARNING** for NUPLAZID at https://www.nuplazid.com/pdf/NUPLAZID_Prescribing_Information.pdf.

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