

**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): October 30, 2019

ACADIA Pharmaceuticals Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation)

000-50768
(Commission
File Number)

06-1376651
(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))

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.0001 per share	ACAD	The Nasdaq Stock Market LLC

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 October 30, 2019, ACADIA Pharmaceuticals Inc. issued a press release announcing its financial results for the third quarter and nine months ended September 30, 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 October 30, 2019.
104	Cover page Interactive Data File (embedded within the Inline XBRL document).

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.

Dated: October 30, 2019

ACADIA Pharmaceuticals Inc.

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

**ACADIA Pharmaceuticals Reports
Third Quarter 2019 Financial Results**

- 3Q19 Net Sales Grew to \$94.6 Million, a 62% Increase Over 3Q18

- 2019 Net Sales Guidance Increased to \$330 to \$340 Million

- Initiated Phase 3 LAVENDER Study of Trofinetide in Rett Syndrome, a Rare
Neurodevelopmental Congenital CNS Disorder

SAN DIEGO, CA, October 30, 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 disorders, today announced its financial results for the third quarter ended September 30, 2019.

“We took a major step forward in fulfilling our mission to improve the lives of patients and their caregivers living with CNS disorders this quarter,” said Steve Davis, ACADIA’s Chief Executive Officer. “More patients are receiving NUPLAZID treatment for their Parkinson’s disease psychosis than ever before and I am proud to report that our commercial efforts drove strong financial performance with net sales of \$94.6 million in the quarter, representing a 62% increase year-over-year. For patients and their families struggling with dementia-related psychosis (DRP), we believe, based on the robustly positive HARMONY Phase 3 data, that pimavanserin has the potential to be one of the first new treatments approved for people with dementia in over fifteen years and the first ever FDA-approved treatment for DRP.”

Recent Highlights

- Achieved the primary endpoint in the pivotal Phase 3 HARMONY study, demonstrating a highly statistically significant longer time to relapse of psychosis with pimavanserin compared to placebo in a planned interim efficacy analysis. Additional details from the study are included in the press release issued by the Company on September 9, 2019. Data from this study will be presented in a late-breaking oral presentation at the Clinical Trials on Alzheimer's Disease (CTAD) meeting on December 4, 2019.
 - Announced that *The Journal of Clinical Psychiatry* published positive Phase 2 CLARITY study results for pimavanserin as adjunctive treatment for patients with major depressive disorder in September 2019. Presented additional positive secondary endpoint data from CLARITY showing pimavanserin significantly improved symptoms of sexual dysfunction compared to placebo in patients with major depressive disorder at the 2019 Psych Congress.
 - Presented positive exploratory data from an open-label Phase 2 study in Parkinson’s disease patients treated with pimavanserin monotherapy or adjunctively with SSRI/SNRI for depressive symptoms at the 2019 International Congress of Parkinson’s Disease and Movement Disorders and at the 2019 Psych Congress.
-

- Initiated the Phase 3 LAVENDER 12-week placebo-controlled study to evaluate the efficacy and safety of trofinetide for girls and young women with Rett syndrome in October 2019.

Financial Results

Revenue

Net sales of NUPLAZID® (pimavanserin) were \$94.6 million for the three months ended September 30, 2019, an increase of 62% as compared to \$58.3 million reported for the three months ended September 30, 2018. Third quarter 2019 gross-to-net decreased to 11.0%, as compared to 13.3% in the third quarter 2018, primarily due to a favorable adjustment to our Medicare accrual. This adjustment resulted in a \$2.2 million increase in third quarter 2019 net sales. For the nine months ended September 30, 2019 and 2018, ACADIA reported net product sales of \$240.8 million and \$164.2 million, respectively.

Research and Development

Research and development expenses for the three months ended September 30, 2019 were \$62.6 million, compared to \$53.1 million for the same period of 2018. For the nine months ended September 30, 2019 and 2018, research and development expenses were \$182.9 million and \$139.0 million, respectively. The increase during the 2019 periods as compared to 2018 was primarily due to development costs associated with trofinetide and additional clinical study costs for pimavanserin.

Selling, General and Administrative

Selling, general and administrative expenses for the three months ended September 30, 2019 were \$72.7 million, compared to \$61.1 million for the same period of 2018. For the nine months ended September 30, 2019 and 2018, selling, general and administrative expenses were \$233.8 million and \$191.5 million, respectively. This increase during the 2019 periods as compared to 2018 was largely due to increased charitable contributions as well as an increase in marketing expense related to our direct-to-consumer advertising campaign and personnel costs.

Net Loss

For the three months ended September 30, 2019, ACADIA reported a net loss of \$42.0 million, or \$0.29 per common share, compared to a net loss of \$62.1 million, or \$0.50 per common share, for the same period in 2018. The net losses for the three months ended September 30, 2019 and 2018 included \$22.0 million and \$20.2 million, respectively, of non-cash stock-based compensation expense. For the nine months ended September 30, 2019, ACADIA reported a net loss of \$182.2 million, or \$1.26 per common share, compared to a net loss of \$179.7 million, or \$1.44 per common share, for the same period in 2018. The net losses for the nine months ended September 30, 2019 and 2018 included \$62.5 million and \$61.2 million, respectively, of non-cash stock-based compensation expense.

Cash and Investments

At September 30, 2019, ACADIA's cash, cash equivalents, and investment securities totaled \$683.8 million, compared to \$473.5 million at December 31, 2018. The increase was primarily due to net proceeds of \$271.5 million from ACADIA's public offering of common stock completed in September 2019 as well as additional cash proceeds from employee option exercises of \$55.1 million.

2019 Financial Guidance

- 2019 NUPLAZID net sales guidance is increased to \$330 to \$340 million from the previous range of \$320 to \$330 million.
- 2019 GAAP R&D guidance is decreased to \$240 to \$250 million from the previous range of \$250 to \$265 million.
- 2019 GAAP SG&A guidance is increased to \$315 to \$325 million from the previous range of \$300 to \$315 million.
- Non-cash stock-based compensation expense guidance of \$80 to \$90 million is unchanged compared to prior guidance.

Conference Call and Webcast Information

ACADIA management will review its third quarter financial results and operations via conference call and webcast today at 4:30 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 2264578). A telephone replay of the conference call may be accessed through November 13, 2019 by dialing 855-859-2056 for callers in the U.S. or Canada and 404-537-3406 for international callers (reference passcode 2264578). 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 November 27, 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 selective serotonin inverse agonist/antagonist 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. NUPLAZID is not FDA-approved for dementia-related psychosis, schizophrenia, major depressive disorder, or depressive symptoms in patients with Parkinson's disease. ACADIA discovered and developed this new chemical entity and holds worldwide rights to develop and commercialize NUPLAZID.

About Trofinetide

Trofinetide is an investigational drug. It is a novel synthetic analog of the amino-terminal tripeptide of IGF-1 designed to treat the core symptoms of Rett syndrome by potentially reducing neuroinflammation and supporting synaptic function. In the central nervous system, IGF-1 is produced by both of the major types of brain cells – neurons and glia. IGF-1 in the brain is critical for both normal development and for response to injury and disease. Trofinetide has been granted Fast Track Status and Orphan Drug Designation in the U.S. and Orphan Drug Designation in Europe for both Rett syndrome and Fragile X syndrome.

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 commercialized the first and only medicine approved for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis. ACADIA also has ongoing clinical development efforts in additional areas with significant unmet need, including dementia-related psychosis, schizophrenia, 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; 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 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, 2018 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 September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Revenues				
Product sales, net	\$ 94,586	\$ 58,305	\$ 240,750	\$ 164,236
Total revenues	<u>94,586</u>	<u>58,305</u>	<u>240,750</u>	<u>164,236</u>
Operating expenses				
Cost of product sales, license fees and royalties (1)	4,689	5,375	14,264	13,938
Research and development (1)	62,622	53,112	182,865	138,980
Selling, general and administrative (1)	72,696	61,089	233,767	191,487
Total operating expenses	<u>140,007</u>	<u>119,576</u>	<u>430,896</u>	<u>344,405</u>
Loss from operations	(45,421)	(61,271)	(190,146)	(180,169)
Interest income, net	2,432	1,229	7,893	3,678
Other expense	747	(1,720)	506	(1,967)
Loss before income taxes	(42,242)	(61,762)	(181,747)	(178,458)
Income tax (benefit) expense	(264)	376	476	1,242
Net loss	<u>\$ (41,978)</u>	<u>\$ (62,138)</u>	<u>\$ (182,223)</u>	<u>\$ (179,700)</u>
Net loss per common share, basic and diluted	<u>\$ (0.29)</u>	<u>\$ (0.50)</u>	<u>\$ (1.26)</u>	<u>\$ (1.44)</u>
Weighted average common shares outstanding, basic and diluted	<u>145,906</u>	<u>125,009</u>	<u>144,741</u>	<u>124,883</u>

(1) Includes the following stock-based compensation expense

Cost of product sales, license fees and royalties	\$ 372	\$ 838	\$ 2,344	\$ 3,025
Research and development	\$ 8,680	\$ 8,066	\$ 24,461	\$ 23,617
Selling, general and administrative	\$ 12,971	\$ 11,265	\$ 35,697	\$ 34,521

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

	<u>September 30,</u> 2019	<u>December 31,</u> 2018
	(unaudited)	
Assets		
Cash, cash equivalents and investment securities	\$ 683,847	\$ 473,520
Accounts receivable, net	30,804	26,090
Interest and other receivables	1,465	1,699
Inventory	4,846	4,070
Prepaid expenses	21,368	20,727
Total current assets	<u>742,330</u>	<u>526,106</u>
Property and equipment, net	3,249	3,309
Operating lease right-of-use assets	9,959	—
Intangible assets, net	2,954	4,062
Restricted cash	4,787	4,826
Other assets	2,307	1,899
Total assets	<u>\$ 765,586</u>	<u>\$ 540,202</u>
Liabilities and stockholders' equity		
Accounts payable	\$ 3,444	\$ 3,167
Accrued liabilities	64,300	56,398
Total current liabilities	<u>67,744</u>	<u>59,565</u>
Operating lease liabilities	6,379	—
Other long-term liabilities	2,174	1,558
Total liabilities	<u>76,297</u>	<u>61,123</u>
Total stockholders' equity	<u>689,289</u>	<u>479,079</u>
Total liabilities and stockholders' equity	<u>\$ 765,586</u>	<u>\$ 540,202</u>

Investor Contact:

ACADIA Pharmaceuticals Inc.

Mark Johnson, CFA

(858) 261-2771

ir@acadia-pharm.com

Media Contact:

ACADIA Pharmaceuticals Inc.

Maurissa Messier

(858) 768-6068

media@acadia-pharm.com