
**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 8, 2018

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 August 8, 2018, ACADIA Pharmaceuticals Inc. issued a press release announcing its financial results for the second quarter and six months ended June 30, 2018. 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 August 8, 2018.

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: August 8, 2018

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

**ACADIA Pharmaceuticals Reports
Second Quarter 2018 Financial Results**

-Second Quarter Net Sales Grew to \$57.1 Million, Representing a 17% Sequential Increase Over 1Q18 and 87% Increase Over 2Q17

-Announced FDA Approval of New Dosing Formulation and Strength of NUPLAZID® (Pimavanserin)

-Expanded ACADIA's Pipeline in Central Nervous System Disorders with Exclusive License Agreement for the North American Development and Commercialization of Trofinetide

SAN DIEGO, CA, August 8, 2018 – 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 second quarter ended June 30, 2018.

“In the second quarter, NUPLAZID delivered 17% revenue growth and 3% sequential volume growth. We remain focused on our initiatives to provide physicians, patients and caregivers access to NUPLAZID’s robust safety and efficacy data and to improve the lives of patients living with Parkinson’s disease psychosis,” said Steve Davis, ACADIA’s President and Chief Executive Officer. “We are building on our foundation of bringing innovative CNS therapies to market with the launch of the 34 mg capsule for NUPLAZID this month and the advancement of our four late-stage clinical programs for pimavanserin with top-line results from our Phase 2 study in major depressive disorder expected in the fourth quarter of 2018. In addition, we are pleased to have recently expanded our pipeline through a license agreement to develop and commercialize trofinetide in North America for the potential treatment of Rett syndrome and other CNS disorders.”

Recent Highlights

- Announced an exclusive license agreement with Neuren Pharmaceuticals (ASX: NEU) for the North American development and commercialization of trofinetide for all indications, including Rett syndrome, a rare neurodevelopmental CNS disorder. Trofinetide is a novel synthetic analog of the amino-terminal tripeptide of IGF-1 designed to treat the core symptoms of Rett syndrome by reducing neuroinflammation and supporting synaptic function.
 - Announced FDA approval of a new 34 mg single capsule formulation of NUPLAZID to help in the treatment of patients living with hallucinations and delusions associated with Parkinson’s disease psychosis.
 - Completed enrollment in the Phase 2 CLARITY study assessing pimavanserin as a potential adjunctive treatment for major depressive disorder.
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- Appointed Austin D. Kim as Executive Vice President, General Counsel and Secretary.

Financial Results

Revenue

Net sales of NUPLAZID were \$57.1 million for the three months ended June 30, 2018, an increase of 87% as compared to \$30.5 million reported for the three months ended June 30, 2017. For the six months ended June 30, 2018 and 2017, ACADIA reported net product sales of \$105.9 million and \$45.8 million, respectively.

Research and Development

Research and development expenses for the three months ended June 30, 2018 were \$46.6 million, compared to \$34.2 million for the same period of 2017. For the six months ended June 30, 2018 and 2017, research and development expenses were \$85.9 million and \$69.6 million, respectively. The increase in research and development expenses during the 2018 period as compared to 2017 was primarily due to additional clinical study costs incurred by the Company as it continues to invest in its life cycle management programs for pimavanserin and costs incurred related to the development of the 34 mg capsule and 10 mg tablet of NUPLAZID.

Selling, General and Administrative

Selling, general and administrative expenses for the three months ended June 30, 2018 were \$69.5 million, compared to \$61.1 million for the same period of 2017. For the six months ended June 30, 2018 and 2017, selling general and administrative expenses were \$130.4 million and \$126.8 million, respectively. The increase in selling, general and administrative expenses during the 2018 period as compared to 2017 was primarily due to an increase in external selling, general and administrative expenses related to the Company's direct-to-consumer disease awareness campaign.

Net Loss

For the three months ended June 30, 2018, ACADIA reported a net loss of \$63.3 million, or \$0.51 per common share, compared to a net loss of \$67.4 million, or \$0.55 per common share, for the same period in 2017. The net losses for the three months ended June 30, 2018 and 2017 included \$20.6 million and \$18.2 million, respectively, of non-cash stock-based compensation expense. For the six months ended June 30, 2018, ACADIA reported a net loss of \$117.6 million, or \$0.94 per common share, compared to a net loss of \$155.3 million, or \$1.27 per common share, for the same period in 2017. The net losses for the six months ended June 30, 2018 and 2017 included \$41.0 million and \$33.8 million, respectively, of non-cash stock-based compensation expense.

Cash and Investments

At June 30, 2018, ACADIA's cash, cash equivalents and investment securities totaled \$256.9 million, compared to \$341.3 million at December 31, 2017.

Financial Guidance

ACADIA is lowering its 2018 NUPLAZID net sales guidance to be between \$210 million and \$225 million from a previous range of \$255 million to \$270 million.

For the third quarter of 2018, ACADIA expects NUPLAZID net sales to be between \$52 million and \$59 million.

ACADIA is lowering its guidance for its year end 2018 cash, cash equivalents and investment securities on its balance sheet to be between \$155 million to \$170 million from previous guidance of over \$200 million. This updated guidance is inclusive of the \$10 million upfront fee and initial research and development expenses for trofinetide.

Conference Call and Webcast Information

ACADIA management will review its first quarter 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 844-821-1109 for participants in the U.S. or Canada and 830-865-2550 for international callers (reference passcode 7987107). A telephone replay of the conference call may be accessed through August 22, 2018 by dialing 855-859-2056 for callers in the U.S. or Canada and 404-537-3406 for international callers (reference passcode 7987107). 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 August 22, 2018.

About NUPLAZID® (pimavanserin)

NUPLAZID is the first FDA-approved treatment for hallucinations and delusions associated with Parkinson's disease psychosis. NUPLAZID is a non-dopaminergic, selective serotonin inverse agonist 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 results from our study in major depressive disorder and the timing of other ongoing clinical studies; the development and commercialization of trofinetide; and guidance for third quarter 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 2018, 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 June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
Revenues				
Product sales, net	\$ 57,063	\$ 30,475	\$ 105,931	\$ 45,761
Total revenues	<u>57,063</u>	<u>30,475</u>	<u>105,931</u>	<u>45,761</u>
Operating expenses				
Cost of product sales, license fees and royalties	5,078	3,206	8,563	6,144
Research and development	46,592	34,180	85,868	69,589
Selling, general and administrative	69,472	61,125	130,398	126,785
Total operating expenses	<u>121,142</u>	<u>98,511</u>	<u>224,829</u>	<u>202,518</u>
Loss from operations	(64,079)	(68,036)	(118,898)	(156,757)
Interest income, net	1,279	993	2,449	1,956
Other expense	(247)	—	(247)	—
Loss before income taxes	(63,047)	(67,043)	(116,696)	(154,801)
Income tax expense	219	398	866	483
Net loss	<u>\$ (63,266)</u>	<u>\$ (67,441)</u>	<u>\$ (117,562)</u>	<u>\$ (155,284)</u>
Net loss per common share, basic and diluted	<u>\$ (0.51)</u>	<u>\$ (0.55)</u>	<u>\$ (0.94)</u>	<u>\$ (1.27)</u>
Weighted average common shares outstanding, basic and diluted	<u>124,910</u>	<u>122,122</u>	<u>124,819</u>	<u>121,888</u>

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

	<u>June 30, 2018</u>	<u>December 31, 2017</u>
	(unaudited)	
Assets		
Cash, cash equivalents and investment securities	\$ 256,855	\$ 341,342
Accounts receivable, net	25,696	17,343
Interest and other receivables	986	1,087
Inventory	4,737	5,248
Prepaid expenses	12,822	8,457
Total current assets	<u>301,096</u>	<u>373,477</u>
Property and equipment, net	2,760	2,662
Intangible assets, net	4,800	5,538
Restricted cash	3,111	2,475
Other assets	3,193	354
Total assets	<u>\$ 314,960</u>	<u>\$ 384,506</u>
Liabilities and stockholders' equity		
Accounts payable	\$ 3,333	\$ 8,786
Accrued liabilities	45,881	40,244
Total current liabilities	<u>49,214</u>	<u>49,030</u>
Long-term liabilities	1,026	191
Total liabilities	<u>50,240</u>	<u>49,221</u>
Total stockholders' equity	<u>264,720</u>	<u>335,285</u>
Total liabilities and stockholders' equity	<u>\$ 314,960</u>	<u>\$ 384,506</u>

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.

NUPLAZID is an atypical antipsychotic indicated for the treatment of 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.

NUPLAZID is available as 34 mg capsules, 17 mg tablets and 10 mg tablets.

For additional Important Safety Information, including Boxed WARNING, please see the full Prescribing Information for NUPLAZID at https://www.nuplazid.com/pdf/NUPLAZID_Prescribing_Information.pdf.

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