# 

# ACADIA Pharmaceuticals Reports First Quarter 2017 Financial Results

# May 9, 2017

SAN DIEGO--(BUSINESS WIRE)--May 9, 2017-- 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 unaudited financial results for the first quarter ended March 31, 2017.

"We're very pleased with our strong start to 2017," said Steve Davis, ACADIA's President and Chief Executive Officer. "The use of NUPLAZID<sup>®</sup> in Parkinson's disease psychosis continues to expand as brand awareness among neurologists, psychiatrists, and other healthcare providers grows. We also continue to advance our ongoing clinical studies in Alzheimer's disease agitation, schizophrenia inadequate response, schizophrenia negative symptoms, and major depressive disorder, and we look forward to moving our Alzheimer's disease psychosis program into Phase III in the second half of 2017."

## **Recent Highlights**

- Net revenue for the first quarter of 2017 of \$15.3 million, an increase of 28% from the fourth quarter of 2016.
- NUPLAZID (pimavanserin) available on Medicare formularies for the treatment of Parkinson's disease psychosis (PD Psychosis); commercial coverage decisions grew to over 90% of commercial lives.
- Expanded penetration into the long-term care market with 25 additional long-term care sales specialists; ACADIA currently has approximately 155 total sales specialists.
- Continued to execute on broad clinical development program with ongoing studies in Alzheimer's disease agitation, schizophrenia inadequate response, schizophrenia negative symptoms, and major depressive disorder.
- Plan to advance Alzheimer's disease psychosis (AD Psychosis) program into Phase III in second half of 2017.
- Presented data on NUPLAZID in PD Psychosis at the American Association for Geriatric Psychiatry Annual Meeting.
- Appointed Michael J. Yang as Executive Vice President, Chief Commercial Officer.

## **Financial Results**

#### Revenue

ACADIA reported NUPLAZID net product sales of \$15.3 million for the three months ended March 31, 2017. NUPLAZID was first made available for prescription starting in May 2016 and there were no similar net product sales for the comparable period of 2016. ACADIA reports product sales when its specialty pharmacy partners dispense NUPLAZID to a patient based on the fulfillment of a prescription or its specialty distributor partners sell NUPLAZID to a government facility, long-term care pharmacy or in-patient hospital pharmacy. As of March 31, 2017, the company had \$4.1 million of deferred product revenue, net of distribution fees, for product it had shipped to its distribution partners that had not yet sold-through the distribution channel. At December 31, 2016, the company had \$2.6 million of deferred product revenue, net of distribution fees.

#### Research and Development

Research and development expenses increased to \$35.4 million for the three months ended March 31, 2017 from \$22.8 million for the comparable period of 2016. This increase was primarily due to increased clinical costs related to studies the company initiated in the fourth quarter of 2016 for indications other than PD Psychosis. The company also incurred additional personnel and related costs associated with its expanded research and development organization during the three months ended March 31, 2017 compared to the same period in 2016.

#### Selling, General and Administrative

Selling, general and administrative expenses increased to \$65.7 million for the three months ended March 31, 2017 from \$27.5 million for the comparable period of 2016. This increase was primarily due to costs incurred to support ACADIA's commercial activities for NUPLAZID and costs related to its specialty sales force that did not exist for the comparable period of 2016 prior to the launch of NUPLAZID.

#### Net Loss

For the three months ended March 31, 2017, ACADIA reported a net loss of \$87.8 million, or \$0.72 per common share, compared to a net loss of \$49.8 million, or \$0.45 per common share, for the comparable period of 2016. The net loss for the three months ended March 31, 2017 included \$15.6 million of non-cash stock-based compensation expense compared to \$12.0 million for the comparable period of 2016.

#### Cash and Investments

At March 31, 2017, ACADIA's cash, cash equivalents, and investment securities totaled \$469.5 million, compared to \$529.0 million at December 31, 2016.

#### Conference Call and Webcast Information

ACADIA management will review its first quarter financial results and operations via conference call and webcast later 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 12435244). A telephone replay of the conference call may be accessed through May 23, 2017 by dialing 855-859-2056 for callers in the U.S. or Canada and 404-537-3406 for international callers (reference passcode 12435244). 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 until May 23, 2017.

#### About NUPLAZID<sup>®</sup> (pimavanserin)

NUPLAZID is the first and only FDA-approved treatment for hallucinations and delusions associated with PD Psychosis. NUPLAZID is a non-dopaminergic, selective serotonin inverse agonist preferentially targeting 5-HT<sub>2A</sub> receptors that are thought to play an important role in PD Psychosis. NUPLAZID is an oral medicine taken once a day with a recommended dose of 34 mg (two 17-mg tablets). ACADIA discovered 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 maintains a website at <u>www.acadia-pharm.com</u> to which we regularly post copies of our press releases as well as additional information and through which interested parties can subscribe to receive e-mail alerts.

#### 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 benefits to be derived from NUPLAZID (pimavanserin); the utility of pimavanserin in indications other than hallucinations and delusions associated with PD Psychosis; and future studies involving pimavanserin. 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 risks and uncertainties inherent in drug discovery, development, 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, 2016 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.

Three Months Ended

#### ACADIA PHARMACEUTICALS INC.

#### CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

(Unaudited)

	March 31,	
	2017	2016
Revenues		
Product sales, net	\$15,286	\$ —
Collaborative revenue	_	4
Total revenues	15,286	4
Operating expenses		
Cost of product sales	2,263	—
License fees and royalties	675	—
Research and development	35,409	22,775
Selling, general and administrative	65,745	27,491
Total operating expenses	104,092	50,266
Loss from operations	(88,806)	(50,262)
Interest income, net	963	500
Net loss	\$(87,843)	\$(49,762)
Net loss per common share, basic and diluted	\$(0.72)	\$(0.45)
Weighted average common shares outstanding, basic and diluted	121,651	111,346

#### ACADIA PHARMACEUTICALS INC.

#### CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

March 31,	December 31,
2017	2016
(unaudited)	

#### Assets

Cash, cash equivalents, and investment securities	\$ 469,481	\$ 529,036
Accounts receivable, net	7,660	5,903
Interest and other receivables	1,859	1,237
Inventory	3,881	4,175
Prepaid expenses	6,872	7,546
Total current assets	489,753	547,897
Property and equipment, net	3,471	3,081
Intangible assets, net	6,646	7,015
Restricted cash	2,475	2,375
Other assets	668	785
Total assets	\$ 503,013	\$ 561,153
Liabilities and stockholders' equity		
Accounts payable	\$ 2,166	\$ 3,912
Accrued liabilities	38,967	36,029
Deferred revenue	4,132	2,644
Total current liabilities	45,265	42,585
Long-term liabilities	224	157
Total liabilities	45,489	42,742
Total stockholders' equity	457,524	518,411
Total liabilities and stockholders' equity	\$ 503,013	\$ 561,153

#### Important Safety Information and Indication for NUPLAZID (pimavanserin) tablets

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 hypersensitivity reaction to pimavanserin or any of its components. Reactions have included rash, urticaria, tongue swelling, circumoral edema, and throat tightness.

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 (≥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: Strong CYP3A4 inhibitors (eg, ketoconazole) increase NUPLAZID concentrations. Reduce the NUPLAZID dose by one-half. Strong CYP3A4 inducers may reduce NUPLAZID exposure, monitor for reduced efficacy. Increase in NUPLAZID dosage may be needed.

Renal Impairment: No dosage adjustment for NUPLAZID is needed in patients with mild to moderate renal impairment. Use of NUPLAZID is not recommended in patients with severe renal impairment.

Hepatic Impairment: Use of NUPLAZID is not recommended in patients with hepatic impairment. NUPLAZID has not been evaluated in this patient population.

Pregnancy: Use of NUPLAZID in pregnant women has not been evaluated and should therefore be used in pregnancy only if the potential benefit justifies the potential risk to the mother and fetus.

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

Dosage and Administration: Recommended dose: 34 mg per day, taken orally as two 17-mg tablets once daily, without titration.

For additional Important Safety Information, including boxed warning, please see the full Prescribing Information for NUPLAZID at <a href="https://www.nuplazid.com/pdf/NUPLAZID">https://www.nuplazid.com/pdf/NUPLAZID</a> Prescribing Information.pdf.

View source version on businesswire.com: http://www.businesswire.com/news/home/20170509006525/en/

Source: ACADIA Pharmaceuticals Inc.

ACADIA Pharmaceuticals Inc. Investor Contact: Lisa Barthelemy, 858-558-2871 ir@acadia-pharm.com or Media Contact: Taft Communications Bob Laverty, 609-558-5570 bob@taftcommunications.com