ACADIA Pharmaceuticals Reports Third Quarter 2017 Financial Results

November 7, 2017

– Third Quarter Net Sales Grew to $35.6 Million

– Company Raises Annual 2017 Net Sales Guidance to Between $124 Million and $127 Million

SAN DIEGO--(BUSINESS WIRE)--Nov. 7, 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 third quarter ended September 30, 2017.

"Our results this quarter reflect strong growth for NUPLAZID for Parkinson's disease psychosis," said Steve Davis, ACADIA's President and Chief Executive Officer. "We also recently advanced our clinical portfolio with the initiation of our Phase III study of pimavanserin for dementia-related psychosis and were pleased to receive FDA Breakthrough Therapy Designation for this program. If this study is successful, we believe pimavanserin will provide an important benefit to patients with dementia-related psychosis who currently have no FDA-approved treatments available to them."

Recent Highlights

- Initiated pivotal Phase III HARMONY Study with pimavanserin in dementia-related psychosis in October 2017.
- FDA granted Breakthrough Therapy Designation to pimavanserin for the treatment of dementia-related psychosis in October 2017. This is the second Breakthrough Therapy Designation for pimavanserin.
- Presented Phase II data with pimavanserin in Alzheimer's disease psychosis at the Symposium, "The Importance of Serotonin in Alzheimer's Disease Psychosis and the Role of Pimavanserin," at the Clinical Trials on Alzheimer's Disease (CTAD) meeting in Boston in November 2017.
- In addition to dementia-related psychosis, ACADIA continues to advance its broad clinical development program with ongoing studies in schizophrenia inadequate response, schizophrenia negative symptoms, and major depressive disorder.

Financial Results

Revenue

Net product sales of NUPLAZID, which was first made available for prescription starting in May 2016, were $35.6 million for the three months ended September 30, 2017 compared to $5.3 million for the three months ended September 30, 2016. For the nine months ended September 30, 2017 and 2016, ACADIA reported NUPLAZID net product sales of $81.3 million and $5.4 million, respectively.

Research and Development

Research and development expenses for the three months ended September 30, 2017 were $36.4 million, compared to $25.8 million for the same period of 2016. For the nine months ended September 30, 2017 and 2016, research and development expenses were $106.0 million and $69.1 million, respectively. The increase in research and development expenses during the 2017 periods as compared to 2016 was primarily due to increased clinical costs related to the clinical studies initiated in the fourth quarter of each of 2016 and 2017. The company also incurred additional personnel and related costs associated with its expanded research and development organization during 2017 as compared to 2016.

Selling, General and Administrative

Selling, general and administrative expenses for the three months ended September 30, 2017 were $62.3 million, compared to $50.5 million for the same period of 2016. For the nine months ended September 30, 2017 and 2016, selling, general and administrative expenses were $189.5 million and $128.8 million, respectively. The increase in selling, general and administrative expenses during the 2017 periods as compared to 2016 was primarily due to costs incurred to support ACADIA's commercial activities for NUPLAZID, including additional personnel and related costs and due to increased charitable contributions.

Net Loss

For the three months ended September 30, 2017, ACADIA reported a net loss of $65.2 million, or $0.53 per common share, compared to a net loss of $71.6 million, or $0.61 per common share, for the same period in 2016. The net losses for the three months ended September 30, 2017 and 2016 included $19.7 million and $14.0 million, respectively, of non-cash stock-based compensation expense. For the nine months ended September 30, 2017, ACADIA reported a net loss of $220.5 million, or $1.81 per common share, compared to a net loss of $192.7 million, or $1.69 per common share, for the same period in 2016. The net losses for the nine months ended September 30, 2017 and 2016 included $53.5 million and $39.8 million, respectively, of non-cash stock-based compensation expense.

Cash and Investments

At September 30, 2017, ACADIA's cash, cash equivalents and investment securities totaled $366.6 million, compared to $529.0 million at December 31, 2016.

2017 Financial Guidance

ACADIA is increasing its revenue guidance and now expects that full-year NUPLAZID net sales for 2017 will be between $124 million and $127 million.

Pro Forma Reconciliation of Sell-Through to Sell-In Method

In the second quarter of 2017 the company began to recognize revenue at the point of sale to its specialty pharmacy and specialty distributor partners, commonly referred to as the “sell-in” revenue recognition method. Previously, ACADIA had deferred the recognition of revenue until it obtained evidence that its specialty partners had dispensed the product to a patient or had sold the product to a government facility, long-term care pharmacy or in-patient hospital pharmacy, commonly referred to as the “sell-through” revenue recognition method. As a result of this change, ACADIA recorded a one-time adjustment of $3.6 million in the second quarter of 2017 to record revenue that had previously been deferred as of March 31, 2017. For comparison purposes, the following table presents NUPLAZID’s pro forma quarterly net product sales under the sell-in method for the three months ended March 31 and June 30, 2017, respectively, if ACADIA had been able to reasonably estimate its allowances for rebates and chargebacks from the time of launch in May 2016. Net sales for the three months ended September 30, 2017, as recorded under the sell-in method, are also presented.

	(in millions)		
	March 31, 2017	**June 30, 2017**	**September 30, 2017**
NUPLAZID net sales, as reported[1]	$ 15.3	$ 30.5	$ 35.6
Difference[2]	1.5	(3.6)	-
NUPLAZID net sales, sell-in method[3]	$ 16.8	$ 26.9	$ 35.6

[1] Represents the net sales, as reported, for the periods presented, including the three months ended March 31, 2017 utilizing the sell-through revenue recognition method and the three months ended June 30, 2017 utilizing the sell-in revenue recognition method together with one-time recognition of previously deferred revenue as a result of the impact of the transition to the sell-in method during the three months ended June 30, 2017.

[2] Represents the impact of recognizing the deferred revenue at period-end, net of allowances for rebates and chargebacks, had the sales been recognized in the quarter which the product was delivered to the specialty pharmacies and distributors.

[3] Represents pro forma results for the three months ended March 31 and June 30, 2017. Results for the three months ended September 30, 2017 are as reported.

Conference Call and Webcast Information

ACADIA management will review its third 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 8898709). A telephone replay of the conference call may be accessed through November 21, 2017 by dialing 855-859-2056 for callers in the U.S. or Canada and 404-537-3406 for international callers (reference passcode 8898709). 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 21, 2017.

About NUPLAZID® (pimavanserin)

NUPLAZID is the first and only FDA-approved treatment for hallucinations and delusions associated with Parkinson's disease (PD) 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 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 www.acadia-pharm.com 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 guidance for full-year 2017 NUPLAZID net sales; the benefits to be derived from NUPLAZID (pimavanserin); and whether NUPLAZID will provide an important benefit to patients with dementia-related psychosis. 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 for 2017, 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, 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.

ACADIA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	**2016**	**2017**	**2016**
Revenues				
Product sales, net	$ 35,578	$ 5,268	$ 81,339	$ 5,365
Collaborative revenue	—	—	—	4
Total revenues	35,578	5,268	81,339	5,369
Operating expenses				
Cost of product sales	2,135	845	6,622	1,371
License fees and royalties	1,078	475	2,735	723
Research and development	36,421	25,813	106,010	69,066
Selling, general and administrative	62,255	50,534	189,523	128,793
Total operating expenses	101,889	77,667	304,890	199,953
Loss from operations	(66,311)	(72,399)	(223,551)	(194,584)
Interest income, net	1,063	786	3,019	1,887
Net loss	$ (65,248)	$ (71,613)	$ (220,532)	$ (192,697)
Net loss per common share, basic and diluted	$ (0.53)	$ (0.61)	$ (1.81)	$ (1.69)
Weighted average common shares outstanding, basic and diluted	122,484	117,497	122,089	114,063

ACADIA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	September 30, 2017	**December 31, 2016**
	(unaudited)	
Assets		
Cash, cash equivalents and investment securities	$ 366,625	$ 529,036
Accounts receivable, net	14,221	5,903
Interest and other receivables	1,033	1,237
Inventory	5,536	4,175
Prepaid expenses	14,557	7,546
Total current assets	401,972	547,897
Property and equipment, net	2,991	3,081
Intangible assets, net	5,907	7,015
Restricted cash	2,475	2,375
Other assets	369	785
Total assets	$ 413,714	$ 561,153
Liabilities and stockholders' equity		
Accounts payable	$ 2,962	$ 3,912
Accrued liabilities	33,181	36,029
Deferred revenue	—	2,644
Total current liabilities	36,143	42,585
Long-term liabilities	245	157
Total liabilities	36,388	42,742
Total stockholders' equity	377,326	518,411
Total liabilities and stockholders' equity	$ 413,714	$ 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 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 (≥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 https://www.nuplazid.com/pdf/NUPLAZID_Prescribing_Information.pdf.

View source version on businesswire.com: http://www.businesswire.com/news/home/20171107006591/en/

Source: ACADIA Pharmaceuticals Inc.

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