# ACADIA Pharmaceuticals Reports Third Quarter 2018 Financial Results

November 6, 2018

*-Third Quarter Net Sales Grew to $58.3 Million*

*-Recently Announced Positive Top-line Results from the Phase 2 CLARITY Trial of Pimavanserin for Adjunctive Treatment for Major Depressive Disorder*

*-FDA Issued Statement Reaffirming the Positive Benefit-Risk Profile of NUPLAZID® for Patients with Hallucinations and Delusions Associated with Parkinson's Disease Psychosis*

*-Launched New Dosing Formulation and Strength of NUPLAZID*

SAN DIEGO--(BUSINESS WIRE)--Nov. 6, 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 third quarter ended September 30, 2018.

"We made significant progress this quarter. On the heels of launching our new 34 mg capsule for NUPLAZID, the FDA issued a public statement reaffirming NUPLAZID's positive benefit-risk profile for treating Parkinson's disease psychosis. These actions, combined with our commercial initiatives, position ACADIA to deliver on NUPLAZID's growth potential," said Steve Davis, ACADIA's President and Chief Executive Officer. "In addition, last week we were very excited to announce robust positive data from our Phase 2 CLARITY study evaluating pimavanserin as an adjunctive therapy for patients with major depressive disorder. These data confirm our confidence that pimavanserin could be a very important new medicine for those who continue to suffer from MDD despite available treatment options. We plan to discuss our results with the FDA and initiate a Phase 3 program in the first half of 2019."

**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).
    - Pimavanserin met the pre-specified primary endpoint of the equally-weighted average results of Stage 1 and Stage 2 by significantly reducing 17-item Hamilton Depression Rating Scale (HAMD-17) total score compared to placebo (p=0.039). In Stage 1, an all-comer parallel comparison to placebo treatment period, pimavanserin showed a highly significant improvement over placebo (p=0.0003; Effect size=0.626).
    - Pimavanserin also demonstrated statistically significant reductions compared to placebo in the pre-specified key secondary endpoint, the Sheehan Disability Scale (SDS), a patient self-assessment of work, family, and social activities (p=0.004).
    - Positive results were also observed on seven additional pre-specified secondary endpoints including responder rate, improvement in sexual function, and reduction in daytime sleepiness.
    - Additional details from the Phase 2 CLARITY results are included in the press release issued by the Company on October 31, 2018.
    - The Company plans to meet with the FDA and initiate a Phase 3 program for pimavanserin as an adjunctive treatment for MDD in the first half of 2019.
- FDA issued a public statement reaffirming the positive benefit-risk profile of NUPLAZID for patients with hallucinations and delusions associated with Parkinson's disease psychosis.
- 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. The Company plans to initiate a Phase 3 trial with trofinetide for Rett syndrome in the second half of 2019.
- Launched a new 34 mg single capsule formulation of NUPLAZID to treat patients living with hallucinations and delusions associated with Parkinson's disease psychosis.
- Appointed Robert Kaper, M.D., as Senior Vice President, Global Head of Medical Affairs, Eliseo Salinas, M.D. M.Sc., as Senior Vice President, Chief Scientific Officer and Head of External Innovation, and Elena Ridloff, CFA, Senior Vice President of Investor Relations, as Interim Chief Financial Officer.

**Financial Results**

*Revenue*
Net sales of NUPLAZID were $58.3 million for the three months ended September 30, 2018, an increase of 64% as compared to $35.6 million reported for the three months ended September 30, 2017. For the nine months ended September 30, 2018 and 2017, ACADIA reported net product sales of $164.2 million and $81.3 million, respectively.

*Research and Development*
Research and development expenses for the three months ended September 30, 2018 were $53.1 million, compared to $36.4 million for the same period of 2017. For the nine months ended September 30, 2018 and 2017, research and development expenses were $139.0 million and $106.0 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.

*Selling, General and Administrative*
Selling, general and administrative expenses for the three months ended September 30, 2018 were $61.1 million, compared to $61.6 million for the same period of 2017. For the nine months ended September 30, 2018 and 2017, selling general and administrative expenses were $191.5 million and $188.4 million, respectively.

*Net Loss*
For the three months ended September 30, 2018, ACADIA reported a net loss of $62.1 million, or $0.50 per common share, compared to a net loss of $65.2 million, or $0.53 per common share, for the same period in 2017. The net losses for the three months ended September 30, 2018 and 2017 included $20.2 million and $19.7 million, respectively, of non-cash stock-based compensation expense. For the nine months ended September 30, 2018, ACADIA reported a net loss of $179.7 million, or $1.44 per common share, compared to a net loss of $220.5 million, or $1.81 per common share, for the same period in 2017. The net losses for the nine months ended September 30, 2018 and 2017 included $61.2 million and $53.5 million, respectively, of non-cash stock-based compensation expense.

*Cash and Investments*
At September 30, 2018, ACADIA's cash, cash equivalents and investment securities totaled $214.1 million, compared to $341.3 million at December 31, 2017.

**Financial Guidance**

ACADIA is updating its 2018 NUPLAZID net sales guidance to be between $220 million and $225 million from a previous range of $210 million to $225 million.

ACADIA is updating its guidance for year end 2018 cash, cash equivalents and investment securities on its balance sheet to be between $160 million to $170 million from a previous range of $155 million to $170 million.

*Conference Call and Webcast Information*
ACADIA management will review its third 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 855-638-4820 for participants in the U.S. or Canada and 443-877-4067 for international callers (reference passcode 3659459). A telephone replay of the conference call may be accessed through November 20, 2018 by dialing 855-859-2056 for callers in the U.S. or Canada and 404-537-3406 for international callers (reference passcode 3659459). 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 20, 2018.

*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 fourth 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)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| **Revenues** | | | | |
| Product sales, net | $ 58,305 | $ 35,578 | $ 164,236 | $ 81,339 |
| Total revenues | 58,305 | 35,578 | 164,236 | 81,339 |
| **Operating expenses** | | | | |
| Cost of product sales, license fees and royalties | 5,375 | 3,213 | 13,938 | 9,357 |
| Research and development | 53,112 | 36,421 | 138,980 | 106,010 |
| Selling, general and administrative | 61,089 | 61,588 | 191,487 | 188,373 |
| Total operating expenses | 119,576 | 101,222 | 344,405 | 303,740 |
| Loss from operations | (61,271) | (65,644) | (180,169) | (222,401) |
| Interest income, net | 1,229 | 1,063 | 3,678 | 3,019 |
| Other expense | (1,720) | — | (1,967) | — |
| Loss before income taxes | (61,762) | (64,581) | (178,458) | (219,382) |
| Income tax expense | 376 | 667 | 1,242 | 1,150 |
| Net loss | $ (62,138) | $ (65,248) | $ (179,700) | $ (220,532) |
| Net loss per common share, basic and diluted | $ (0.50) | $ (0.53) | $ (1.44) | $ (1.81) |
| Weighted average common shares outstanding, basic and diluted | 125,009 | 122,484 | 124,883 | 122,089 |

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

| | September 30, 2018 | December 31, 2017 |
|---|---|---|
| | (unaudited) | |
| **Assets** | | |
| Cash, cash equivalents and investment securities | $ 214,136 | $ 341,342 |
| Accounts receivable, net | 19,958 | 17,343 |
| Interest and other receivables | 724 | 1,087 |
| Inventory | 4,347 | 5,248 |
| Prepaid expenses | 14,951 | 8,457 |
| Total current assets | 254,116 | 373,477 |
| Property and equipment, net | 3,372 | 2,662 |
| Intangible assets, net | 4,431 | 5,538 |
| Restricted cash | 3,111 | 2,475 |
| Other assets | 1,426 | 354 |
| Total assets | $ 266,456 | $ 384,506 |
| **Liabilities and stockholders' equity** | | |
| Accounts payable | $ 2,955 | $ 8,786 |
| Accrued liabilities | 38,852 | 40,244 |
| Total current liabilities | 41,807 | 49,030 |
| Long-term liabilities | 1,209 | 191 |
| Total liabilities | 43,016 | 49,221 |
| Total stockholders' equity | 223,440 | 335,285 |
| Total liabilities and stockholders' equity | $ 266,456 | $ 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.**

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: 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20181106005884/en/

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