ACADIA Pharmaceuticals Reports Third Quarter 2019 Financial Results

October 30, 2019

- 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--(BUSINESS WIRE)--Oct. 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)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018

Revenues				
Product sales, net	$ 94,586	$ 58,305	$ 240,750	$ 164,236
Total revenues	94,586	58,305	240,750	164,236
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	140,007	119,576	430,896	344,405
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	$ (41,978)	$ (62,138)	$ (182,223)	$ (179,700)
Net loss per common share, basic and diluted	$ (0.29)	$ (0.50)	$ (1.26)	$ (1.44)
Weighted average common shares outstanding, basic and diluted	145,906	125,009	144,741	124,883

[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)

	September 30, 2019	December 31, 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	742,330	526,106
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	$ 765,586	$ 540,202
Liabilities and stockholders' equity		
Accounts payable	$ 3,444	$ 3,167
Accrued liabilities	64,300	56,398
Total current liabilities	67,744	59,565
Operating lease liabilities	6,379	—
Other long-term liabilities	2,174	1,558
Total liabilities	76,297	61,123
Total stockholders' equity	689,289	479,079
Total liabilities and stockholders' equity	$ 765,586	$ 540,202

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