Acadia Pharmaceuticals Reports Fourth Quarter and Full Year 2020 Financial Results

February 24, 2021

- Full year 2020 net sales grew to $441.8 million, a 30% increase over 2019

- Upcoming PDUFA action date of April 3, 2021 for supplemental New Drug Application for pimavanserin for the treatment of hallucinations and delusions associated with dementia-related psychosis

SAN DIEGO--(BUSINESS WIRE)--Feb. 24, 2021-- Acadia Pharmaceuticals Inc. (Nasdaq: ACAD) today announced financial results for the fourth quarter and full year ended December 31, 2020.

“Acadia delivered strong financial results in the fourth quarter and full year 2020, driven by robust sales of NUPLAZID in Parkinson’s disease psychosis. Additionally, we made significant advancements in two Phase 3 programs and further expanded our pipeline in pain and neuropsychiatry through strategic business development,” said Steve Davis, Chief Executive Officer. “In 2021, we are focused on delivering continued growth of NUPLAZID, the upcoming potential approval and launch of pimavanserin for dementia-related psychosis and advancing our business development strategy.”

Company Highlights

- Upcoming PDUFA (Prescription Drug User Fee Act) date of April 3, 2021 for supplemental New Drug Application for pimavanserin for the treatment of hallucinations and delusions associated with dementia-related psychosis.
- Top-line results from Phase 3 LAVENDER study evaluating trofinetide for the treatment of Rett syndrome expected in the fourth quarter of 2021.
- Two Phase 2 clinical studies evaluating ACP-044, a novel, first-in-class, orally administered, non-opioid analgesic, in acute and chronic pain to commence in first half of 2021. A bunionectomy study is expected to initiate in the first quarter of 2021 and an osteoarthritis study is expected to initiate in the second quarter of 2021.
- In November 2020, the FDA approved a label update to allow the NUPLAZID capsule to be sprinkled on certain foods. This is an important feature for patients who take oral medications and may have difficulty swallowing; a potential issue for Parkinson’s disease patients and in the elderly in general.
- Kathie Bishop, Ph.D., joined Acadia as Senior Vice President, Head of Rare Disease and Diann Potestio joined Acadia as Senior Vice President, Market Access, Reimbursement and Channel Strategy.

Financial Results

Revenue
Net sales of NUPLAZID® (pimavanserin) were $121.0 million for the fourth quarter of 2020, an increase of 23% as compared to $98.3 million reported for the fourth quarter of 2019. For the years ended December 31, 2020 and 2019, Acadia reported net product sales of $441.8 million and $339.1 million, respectively, an increase of 30% year-over-year.

Research and Development
Research and development expenses for the fourth quarter of 2020 were $62.1 million, compared to $57.5 million for the same period of 2019. For the years ended December 31, 2020 and 2019, research and development expenses were $319.1 million and $240.4 million, respectively. The increase in full year 2020 was primarily due to the upfront expenses of $52.8 million related to the acquisition of CerSci Therapeutics and a $10.0 million upfront payment to Vanderbilt University related to the license agreement and collaboration for novel therapeutic programs targeting muscarinic M1 receptors.

Selling, General and Administrative
Selling, general and administrative expenses for the fourth quarter of 2020 were $120.8 million, compared to $91.9 million for the same period of 2019. For the years ended December 31, 2020 and 2019, selling, general and administrative expenses were $388.7 million and $325.6 million, respectively. This increase during the 2020 period as compared to 2019 was primarily due to increased advertising and promotional costs, dementia-related psychosis launch preparation expenses, as well as an increase in personnel and related costs.

Net Loss
For the fourth quarter of 2020, Acadia reported a net loss of $66.8 million, or $0.42 per common share, compared to a net loss of $53.0 million, or $0.34 per common share, for the same period in 2019. The net losses for the fourth quarters of 2020 and 2019 included $21.2 million and $19.8 million, respectively, of non-cash stock-based compensation expense. For the year ended December 31, 2020, Acadia reported a net loss of $281.6 million, or $1.79 per common share, compared to a net loss of $235.3 million, or $1.60 per common share, for the same period in 2019. The net losses for the years ended December 31, 2020 and 2019 included $84.4 million and $82.3 million, respectively, of non-cash stock-based compensation expense.

Cash and Investments
At December 31, 2020, Acadia’s cash, cash equivalents, and investment securities totaled $632.0 million, compared to $697.4 million at December 31,

2019.

2021 Financial Guidance

- Net sales guidance for NUPLAZID in Parkinson's disease psychosis (PDP) of $510 to $550 million. As this is the potential launch year for dementia-related psychosis (DRP), the Company is not including revenue projections for DRP in 2021 net sales guidance.
- GAAP R&D guidance of $300 to $320 million reflects the progression of candidates in five clinical indications this year. This guidance includes approximately $30 million of share-based compensation expense.
- GAAP SG&A guidance of $560 to $590 million reflects a similar level of investment to 2020 in PDP activities, together with additional investments associated with a potential DRP launch. This guidance includes approximately $60 million of share-based compensation expense.

Conference Call and Webcast Information
Acadia management will review its fourth quarter and full year 2020 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 United States or Canada and 443-877-4067 for international callers (reference passcode 9576845). A telephone replay of the conference call may be accessed through March 10, 2021 by dialing 855-859-2056 for callers in the United States or Canada and 404-537-3406 for international callers (reference passcode 9576845). 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 March 24, 2021.

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 trailblazing breakthroughs in neuroscience to elevate life. For more than 25 years we have been working at the forefront of healthcare to bring vital solutions to people who need them most. We developed and commercialized the first and only approved therapy for hallucinations and delusions associated with Parkinson's disease psychosis. Our late-stage development efforts are focused on dementia-related psychosis, negative symptoms of schizophrenia and Rett syndrome, and in early-stage clinical research we are exploring novel approaches to pain management, and cognition and neuropsychiatric symptoms in central nervous system disorders. For more information, visit us at www.acadia-pharm.com and follow us on LinkedIn.

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 2021 NUPLAZID net sales for Parkinson's disease psychosis only 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 2021, 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, 2019 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 December 31,		Years Ended December 31,	
	2020	2019	2020	2019
Revenues				
Product sales, net	$ 121,007	$ 98,326	$ 441,755	$ 339,076
Total revenues	121,007	98,326	441,755	339,076
Operating expenses				
Cost of product sales, license fees and royalties [1]	5,301	5,334	20,550	19,598
Research and development [1]	62,116	57,520	319,130	240,385
Selling, general and administrative [1]	120,752	91,871	388,661	325,638
Total operating expenses	188,169	154,725	728,341	585,621
Loss from operations	(67,162)	(56,399)	(286,586)	(246,545)
Interest income, net	554	3,272	6,610	11,165
Other income (expense)	265	491	(997)	997
Loss before income taxes	(66,343)	(52,636)	(280,973)	(234,383)
Income tax (benefit) expense	417	400	611	876
Net loss	$ (66,760)	$ (53,036)	$ (281,584)	$ (235,259)
Net loss per common share, basic and diluted	$ (0.42)	$ (0.34)	$ (1.79)	$ (1.60)
Weighted average common shares outstanding, basic and diluted	159,263	154,492	157,331	147,199

[1] Includes the following share-based compensation expenses

Cost of product sales, license fees and royalties	$ 545	$ 592	$ 2,632	$ 2,936
Research and development	$ 7,669	$ 8,072	$ 31,314	$ 32,533
Selling, general and administrative	$ 12,981	$ 11,099	$ 50,476	$ 46,796

ACADIA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	December 31, 2020	December 31, 2019
	(unaudited)	
Assets		
Cash, cash equivalents and investment securities	$ 631,958	$ 697,429
Accounts receivable, net	48,247	35,781
Interest and other receivables	2,035	2,093
Inventory	9,682	6,341
Prepaid expenses	25,694	18,606
Total current assets	717,616	760,250
Property and equipment, net	9,161	3,180
Operating lease right-of-use assets	47,283	9,524
Intangible assets, net	1,108	2,585
Restricted cash	5,770	4,787
Other assets	1,678	2,857
Total assets	$ 782,616	$ 783,183
Liabilities and stockholders' equity		
Accounts payable	$ 8,493	$ 7,222
Accrued liabilities	97,474	67,604
Total current liabilities	105,967	74,826
Operating lease liabilities	44,460	6,361
Long-term liabilities	5,180	2,861
Total liabilities	155,607	84,048
Total stockholders' equity	627,009	699,135
Total liabilities and stockholders' equity	$ 782,616	$ 783,183

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