Acadia Pharmaceuticals Reports Fourth Quarter and Full Year 2021 Financial Results

February 28, 2022

- Full year 2021 net sales grew to $484.1 million, a 10% increase over 2020

- Resubmitted sNDA for pimavanserin for the treatment of Alzheimer's disease psychosis

- Delivered positive top-line results from the pivotal Phase 3 Lavender trial evaluating trofinetide for the treatment of Rett syndrome

SAN DIEGO--(BUSINESS WIRE)--Feb. 28, 2022-- Acadia Pharmaceuticals Inc. (Nasdaq: ACAD) today announced financial results for the fourth quarter and full year ended December 31, 2021.

“Acadia delivered strong fourth quarter and full year results with an increase in net sales of 10 percent year-over-year, driven by growth in both NUPLAZID prescriptions and market share,” said Steve Davis, Chief Executive Officer. “We recently resubmitted our sNDA for pimavanserin for Alzheimer’s disease psychosis to the FDA. In addition, this year we plan to submit an NDA for trofinetide for the treatment of Rett syndrome, complete enrollment in our pivotal ADVANCE-2 study for pimavanserin for the negative symptoms of schizophrenia, and deliver results from two Phase 2 studies for ACP-044 in postoperative and osteoarthritis pain.”

Company Highlights

- Grew NUPLAZID® (pimavanserin) total prescriptions and market share, and outperformed other branded drugs in neurology, the Parkinson’s market, and long-term care facilities.
- Resubmitted supplemental New Drug Application (sNDA) of NUPLAZID (pimavanserin) for the treatment of the hallucinations and delusions associated with Alzheimer’s disease psychosis (ADP) to the U.S. Food and Drug Administration (FDA).
- Delivered positive top-line results from the pivotal Phase 3 Lavender study of trofinetide in Rett syndrome and plan to submit an NDA to the FDA around mid-year 2022.
- Announced collaboration with Stoke Therapeutics to pursue multiple RNA-based treatments for severe and rare genetic neurodevelopmental diseases for SYNGAP1 syndrome, Rett syndrome (MECP2), and an undisclosed neurodevelopmental target of mutual interest.
- Expect top-line results from a Phase 2 study evaluating ACP-044 for the treatment of postoperative pain following bunionectomy surgery around the end of the first quarter of 2022.
- Published results from the ADVANCE study evaluating pimavanserin for the treatment of the negative symptoms of schizophrenia in *The Lancet Psychiatry*.

Financial Results

Revenue

Net sales of NUPLAZID (pimavanserin) were $130.8 million for the fourth quarter of 2021, an increase of 8% as compared to $121.0 million reported for the fourth quarter of 2020. For the years ended December 31, 2021 and 2020, Acadia reported net product sales of $484.1 million and $441.8 million, respectively, an increase of 10% year-over-year.

Research and Development

Research and development expenses for the fourth quarter of 2021 were $67.1 million, compared to $62.1 million for the same period of 2020. For the years ended December 31, 2021 and 2020, research and development expenses were $239.4 million and $319.1 million, respectively. The decrease was primarily due to the $52.8 million in upfront consideration and transaction costs paid for the acquisition of CerSci and $10.0 million upfront payment to Vanderbilt University for the M1 PAM program in 2020, partially offset by an increase in costs related to trofinetide.

Selling, General and Administrative

Selling, general and administrative expenses for the fourth quarter of 2021 were $105.8 million, compared to $120.8 million for the same period of 2020. For the years ended December 31, 2021 and 2020, selling, general and administrative expenses were $396.0 million and $388.7 million, respectively.

Net Loss

For the fourth quarter of 2021, Acadia reported a net loss of $43.1 million, or $0.27 per common share, compared to a net loss of $66.8 million, or $0.42 per common share, for the same period in 2020. The net losses for the fourth quarters of 2021 and 2020 included $12.9 million and $21.2

million, respectively, of non-cash stock-based compensation expense. For the year ended December 31, 2021, Acadia reported a net loss of $167.9 million, or $1.05 per common share, compared to a net loss of $281.6 million, or $1.79 per common share, for the same period in 2020. The net losses for the years ended December 31, 2021 and 2020 included $63.6 million and $84.4 million, respectively, of non-cash stock-based compensation expense.

Cash and Investments

At December 31, 2021, Acadia's cash, cash equivalents, and investment securities totaled $520.7 million, compared to $632.0 million at December 31, 2020.

2022 Financial Guidance

- NUPLAZID net sales guidance in Parkinson's disease psychosis is $510 to $560 million.
- GAAP R&D guidance is $355 to $375 million and includes approximately $25 million of stock-based compensation expense.
- GAAP SG&A guidance is $360 to $380 million and includes approximately $45 million of stock-based compensation expense.

Conference Call and Webcast Information

Acadia management will review its fourth quarter and full year 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 6887457). A telephone replay of the conference call may be accessed through March 14, 2022 by dialing 855-859-2056 for callers in the United States or Canada and 404-537-3406 for international callers (reference passcode 6887457). 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 March 28, 2022.

About NUPLAZID® (pimavanserin)

Pimavanserin is a selective serotonin inverse agonist and antagonist preferentially targeting 5-HT_{2A} receptors. These receptors are thought to play an important role in neuropsychiatric disorders. In vitro, pimavanserin demonstrated no appreciable binding affinity for dopamine (including D2), histamine, muscarinic, or adrenergic receptors. Pimavanserin was approved for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis by the U.S. Food and Drug Administration in April 2016 under the trade name NUPLAZID. NUPLAZID is not approved for Alzheimer's disease psychosis. In addition, Acadia is developing pimavanserin in other neuropsychiatric conditions.

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. Trofinetide is thought to stimulate synaptic maturation and overcome the synaptic and neuronal immaturities that are characteristic of Rett syndrome pathophysiology. 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 shown to inhibit the production of inflammatory cytokines, inhibit the overactivation of microglia and astrocytes, and increase the amount of available IGF-1 that can bind to IGF-1 receptors. Trofinetide has been granted Fast Track Status and Orphan Drug Designation for Rett syndrome and has also been granted Rare Pediatric Disease (RPD) designation by the FDA.

About Acadia Pharmaceuticals

Acadia is advancing 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 treating psychosis in patients with dementia, the negative symptoms of schizophrenia and Rett syndrome. Our early-stage development efforts are focused on novel approaches to pain management, cognition and neuropsychiatric symptoms in central nervous system disorders. For more information, visit us at www.acadia-pharm.com and follow us on LinkedIn and Twitter.

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 2022 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 2022, 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, 2020 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,	
	2021	**2020**	**2021**	**2020**
Revenues				
Product sales, net	$ 130,758	$ 121,007	$ 484,145	$ 441,755
Total revenues	130,758	121,007	484,145	441,755
Operating expenses				
Cost of product sales, license fees and royalties [(1)]	2,561	5,301	19,141	20,550
Research and development [(1)]	67,084	62,116	239,415	319,130
Selling, general and administrative [(1)]	105,770	120,752	396,028	388,661
Total operating expenses	175,415	188,169	654,584	728,341
Loss from operations	(44,657)	(67,162)	(170,439)	(286,586)
Interest income, net	129	554	591	6,610
Other income (expense)	1,623	265	2,329	(997)
Loss before income taxes	(42,905)	(66,343)	(167,519)	(280,973)
Income tax (benefit) expense	189	417	351	611
Net loss	$ (43,094)	$ (66,760)	$ (167,870)	$ (281,584)
Net loss per common share, basic and diluted	$ (0.27)	$ (0.42)	$ (1.05)	$ (1.79)
Weighted average common shares outstanding, basic and diluted	160,866	159,263	160,493	157,331

[(1)] Includes the following share-based compensation expenses

Cost of product sales, license fees and royalties	$ 261	$ 545	$ 1,286	$ 2,632
Research and development	$ 4,644	$ 7,669	$ 21,969	$ 31,314
Selling, general and administrative	$ 7,975	$ 12,981	$ 40,360	$ 50,476

ACADIA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	December 31, 2021	December 31, 2020
	(unaudited)	
Assets		
Cash, cash equivalents and investment securities	$ 520,706	$ 631,958
Accounts receivable, net	64,366	48,247
Interest and other receivables	978	2,035
Inventory	7,881	9,682
Prepaid expenses	23,892	25,694
Total current assets	617,823	717,616
Property and equipment, net	8,047	9,161
Operating lease right-of-use assets	58,268	47,283
Intangible assets, net	—	1,108
Restricted cash	5,770	5,770
Long-term inventory	6,217	—
Other assets	3,997	1,678
Total assets	$ 700,122	$ 782,616
Liabilities and stockholders' equity		
Accounts payable	$ 6,876	$ 8,493
Accrued liabilities	89,192	97,474
Total current liabilities	96,068	105,967
Operating lease liabilities	56,126	44,460
Long-term liabilities	7,034	5,180

Total liabilities	159,228	155,607
Total stockholders' equity	540,894	627,009
Total liabilities and stockholders' equity	$ 700,122	$ 782,616

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