Acadia Pharmaceuticals Reports Third Quarter 2022 Financial Results

November 2, 2022

- 3Q22 net sales of $130.7 million

- Prescription Drug User Fee Act action date set for March 12, 2023 for trofinetide for the treatment of Rett syndrome

SAN DIEGO--(BUSINESS WIRE)--Nov. 2, 2022-- Acadia Pharmaceuticals Inc. (Nasdaq: ACAD), today announced its financial results for the third quarter ended September 30, 2022.

NUPLAZID delivered net sales of $130.7 million in the third quarter of 2022, driven by sequential demand growth of 2% and an acceleration of growth in the long-term care (LTC) channel, offset by a reduction of in-channel inventory of approximately $7 million.

“Our third quarter results reflect continued growth in demand for NUPLAZID, driven by early signs of improvement in the long-term care channel,” said Steve Davis, Chief Executive Officer. “In the quarter we announced that our new drug application of trofinetide for the treatment of Rett syndrome has been accepted for filing by the FDA and granted a priority review. Furthermore, we continued to advance our late and early-stage portfolio, including our Phase 3 program for pimavanserin for the treatment of the negative symptoms of schizophrenia and our Phase 1 ACP-204 program for neuropsychiatric indications.”

Company Updates

- Trofinetide New Drug Application (NDA) for the treatment of Rett syndrome was accepted for filing by the U.S. Food and Drug Administration (FDA). The FDA granted a priority review and assigned a PDUFA (Prescription Drug User Fee Act) action date of March 12, 2023, and informed the company that they are not planning to hold an Advisory Committee meeting.
- Presented clinical data for trofinetide at medical congresses in October, including the positive Phase 3 Lavender results and the Daffodil study in girls aged 2-4 with Rett syndrome, at the *51st Annual Meeting of the Child Neurology Society (CNS) in Cincinnati, OH and the National Organization for Rare Diseases (NORD) & Orphan Products 2022 Summit* in Washington, DC.
- Continue to expect enrollment to complete in ADVANCE-2, a Phase 3 study evaluating pimavanserin for the negative symptoms of schizophrenia, around mid-year 2023.
- Announced that Acadia’s President Serge Stankovic, M.D., M.S.P.H. will retire at the end of the year. A search for a successor to Dr. Stankovic is ongoing. Following his retirement, Dr. Stankovic will provide consulting and advisory services for Acadia on a part-time basis.
- Appointed Adora Ndu, Pharm.D., J.D. to Acadia’s Board of Directors. Dr. Ndu is a biopharma executive with significant regulatory and clinical development experience, combined with an extensive background in rare disease that nicely complements the skill sets of Acadia’s current Board membership.

Financial Results

Revenue

Net sales of NUPLAZID® (pimavanserin) were $130.7 million for the three months ended September 30, 2022, a decrease of 1% as compared to $131.6 million reported for the three months ended September 30, 2021. Net sales for the quarter were driven by sequential demand growth of 2% and an acceleration of growth in the LTC channel, offset by a reduction of in-channel inventory of approximately $7 million. For the nine months ended September 30, 2022, Acadia reported net product sales of $380.7 million, an increase of approximately 8% as compared to $353.4 million reported for the nine months ended September 30, 2021.

Research and Development

Research and development expenses for the three months ended September 30, 2022 were $81.3 million, compared to $58.6 million for the same period of 2021. The increase in research and development expenses during the quarter was primarily due to a $10 million milestone payment accrued to Neuren upon acceptance of the trofinetide NDA filing, as well as increased costs of manufacturing activities for trofinetide and the development of early-stage programs. For the nine months ended September 30, 2022 and 2021, research and development expenses were $285.8 million and $172.5 million. The increase was primarily due to the $60 million upfront payment made to Stoke Therapeutics for a license and collaboration agreement and the previously mentioned $10 million milestone as well as increased costs for trofinetide and early-stage programs.

Selling, General and Administrative

Selling, general and administrative expenses for the three months ended September 30, 2022 were $78.1 million, compared to $81.7 million for the

same period of 2021. For the nine months ended September 30, 2022 and 2021, selling, general and administrative expenses were $264.7 million and $290.1 million, respectively. The decrease was primarily due to decreased advertising and promotional costs.

Net Loss

For the three months ended September 30, 2022, Acadia reported a net loss of $27.2 million, or $0.17 per common share, compared to a net loss of $14.5 million, or $0.09 per common share, for the same period in 2021. The net losses for the three months ended September 30, 2022 and 2021 included $18.3 million and $15.5 million, respectively, of non-cash stock-based compensation expense. For the nine months ended September 30, 2022, Acadia reported a net loss of $174.3 million, or $1.08 per common share, compared to a net loss of $124.8 million, or $0.78 per common share, for the same period in 2021. The increase was mainly due to the upfront and milestone payments made for license and collaboration agreements in 2022. The net losses for the nine months ended September 30, 2022 and 2021 included $53.8 million and $50.7 million, respectively, of non-cash stock-based compensation expense.

Cash and Investments

At September 30, 2022, Acadia's cash, cash equivalents, and investment securities totaled $436.6 million, compared to $520.7 million at December 31, 2021.

2022 Financial Guidance

- NUPLAZID net sales guidance is updated to $510 to $520 million from the previous range of $510 to $540 million.
- GAAP R&D guidance is updated to $345 to $355 million from the previous range of $340 to $360 million, which includes approximately $25 million of stock-based compensation expense.
- GAAP SG&A guidance is updated to $365 to $375 million from the previous range of $360 to $380 million, which includes approximately $45 million of stock-based compensation expense.

Conference Call and Webcast Information

The conference call may be accessed by registering for the call here. Once registered, participants will receive an email with the dial-in number and unique PIN number to use for accessing the call. The registration link will also be available on Acadia's website, www.acadia.com under the investors section and will be archived there until December 7, 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. 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.

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 clinical-stage development efforts are focused on treating the negative symptoms of schizophrenia, Rett syndrome and neuropsychiatric symptoms in central nervous system disorders. For more information, visit us at www.acadia.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, 2021 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,	
	2022	**2021**	**2022**	**2021**
Revenues				
Product sales, net	$ 130,714	$ 131,612	$ 380,745	$ 353,387
Total revenues	130,714	131,612	380,745	353,387
Operating expenses				
Cost of product sales, license fees and royalties [(1)]	2,136	6,682	7,753	16,580
Research and development [(1)]	81,336	58,565	285,837	172,473
Selling, general and administrative [(1)]	78,108	81,666	264,688	290,116
Total operating expenses	161,580	146,913	558,278	479,169
Loss from operations	(30,866)	(15,301)	(177,533)	(125,782)
Interest income, net	2,295	129	2,980	462
Other income	2,156	383	1,999	706
Loss before income taxes	(26,415)	(14,789)	(172,554)	(124,614)
Income tax expense (benefit)	768	(332)	1,696	162
Net loss	$ (27,183)	$ (14,457)	$ (174,250)	$ (124,776)
Net loss per common share, basic and diluted	$ (0.17)	$ (0.09)	$ (1.08)	$ (0.78)
Weighted average common shares outstanding, basic and diluted	161,852	160,663	161,580	159,651

[(1)] Includes the following stock-based compensation expense

Cost of product sales, license fees and royalties	$ 344	$ 439	$ 1,013	$ 1,025

Research and development	$ 6,452	$ 5,176	$ 19,148	$ 17,325
Selling, general and administrative	$ 11,516	$ 9,931	$ 33,626	$ 32,385

ACADIA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	September 30, 2022	**December 31, 2021**
	(unaudited)	
Assets		
Cash, cash equivalents and investment securities	$ 436,579	$ 520,706
Accounts receivable, net	55,733	64,366
Interest and other receivables	403	978
Inventory	5,844	7,881
Prepaid expenses	22,993	23,892
Total current assets	521,552	617,823
Property and equipment, net	6,510	8,047
Operating lease right-of-use assets	56,624	58,268
Restricted cash	5,770	5,770
Long-term inventory	5,992	6,217
Other assets	6,043	3,997
Total assets	$ 602,491	$ 700,122
Liabilities and stockholders' equity		
Accounts payable	$ 10,008	$ 6,876
Accrued liabilities	106,562	89,192
Total current liabilities	116,570	96,068
Operating lease liabilities	53,769	56,126
Other long-term liabilities	6,466	7,034
Total liabilities	176,805	159,228

Total stockholders' equity	425,686	540,894
Total liabilities and stockholders' equity	$ 602,491	$ 700,122

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