Acadia Pharmaceuticals Reports First Quarter 2022 Financial Results

May 4, 2022

- 1Q22 net sales of $115.5 million, an 8% increase over 1Q21

- Reiterating FY22 net sales guidance of $510 to $560 million

- FDA Advisory Committee meeting to review sNDA for pimavanserin for the treatment of ADP scheduled for June 17, 2022

SAN DIEGO--(BUSINESS WIRE)--May 4, 2022-- Acadia Pharmaceuticals Inc. (Nasdaq: ACAD), today announced its financial results for the first quarter ended March 31, 2022.

“NUPLAZID continued to deliver year over year growth in the first quarter of 2022,” said Steve Davis, Chief Executive Officer. “In the near term, we are focused on preparing for the upcoming Advisory Committee meeting in connection with our resubmitted sNDA for pimavanserin in Alzheimer’s disease psychosis. In addition, we have aligned with the FDA on the contents of our upcoming NDA submission for trofinetide in Rett syndrome and continue to enroll patients in our ongoing Phase 3 study evaluating pimavanserin for the negative symptoms of schizophrenia.”

Company Highlights

- The U.S. Food and Drug Administration (FDA) Advisory Committee meeting is scheduled for June 17, 2022 to review the resubmission of the supplemental New Drug Application (sNDA) for pimavanserin for the treatment of hallucinations and delusions associated with Alzheimer’s disease psychosis (ADP).
- The FDA is targeting an August 4, 2022 action date for the resubmitted sNDA for pimavanserin for the treatment of ADP.
- Trofinetide for the treatment of Rett syndrome remains on track for an NDA submission around mid-year 2022.
- Late-breaker oral presentation on the efficacy and safety data from the Phase 3 Lavender study of trofinetide was presented at the 2022 American Academy of Neurology Annual Meeting (AAN) on April 5, 2022.
- Parag Meswani joined Acadia as Senior Vice President, Trofinetide - Rare Disease Franchise to lead the trofinetide commercial effort. In addition, Holly Valdiviez joined Acadia as Senior Vice President, Head of Sales for NUPLAZID. Parag and Holly have joined Acadia’s Executive Management Committee.

Financial Results

Revenue

Net sales of NUPLAZID (pimavanserin) were $115.5 million for the three months ended March 31, 2022, an increase of 8% as compared to $106.6 million reported for the three months ended March 31, 2021.

Research and Development

Research and development expenses for the three months ended March 31, 2022 were $128.9 million, compared to $57.0 million for the same period of 2021. This increase was primarily due to expensing of the $60.0 million upfront payment made to Stoke Therapeutics under the license and collaboration agreement made in January 2022.

Selling, General and Administrative

Selling, general and administrative expenses for the three months ended March 31, 2022 were $96.7 million, compared to $111.7 million for the same period of 2021. This decrease was primarily due to decreased advertising and promotional costs and decreased personnel expenses.

Net Loss

For the three months ended March 31, 2022, Acadia reported a net loss of $113.1 million, or $0.70 per common share, compared to a net loss of $66.4 million, or $0.42 per common share, for the same period in 2021. This increase in net loss was primarily due to expensing of the $60.0 million upfront payment made to Stoke Therapeutics under the license and collaboration agreement made in January 2022. The net losses for the three months ended March 31, 2022 and 2021 included $15.0 million and $13.2 million, respectively, of non-cash stock-based compensation expense.

Cash and Investments

At March 31, 2022, Acadia’s cash, cash equivalents, and investment securities totaled $446.0 million, compared to $520.7 million at December 31, 2021.

2022 Financial Guidance

Acadia is reiterating its previously provided guidance ranges:

- NUPLAZID net sales guidance of $510 to $560 million.
- GAAP R&D guidance of $355 to $375 million, which includes approximately $25 million of stock-based compensation

expense.
- GAAP SG&A guidance of $360 to $380 million, which includes approximately $45 million of stock-based compensation expense.

Conference Call and Webcast Information

Acadia management will review its first 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 United States or Canada and 443-877-4067 for international callers (reference passcode 6989476). A telephone replay of the conference call may be accessed through May 19, 2022 by dialing 855-859-2056 for callers in the United States or Canada and 404-537-3406 for international callers (reference passcode 6989476). 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 June 1, 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, 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 March 31,	
	2022	**2021**
Revenues		

Product sales, net	$ 115,468	$ 106,554
Total revenues	115,468	106,554
Operating expenses		
Cost of product sales, license fees and royalties [1]	2,950	4,692
Research and development [1]	128,855	56,973
Selling, general and administrative [1]	96,679	111,661
Total operating expenses	228,484	173,326
Loss from operations	(113,016)	(66,772)
Interest income, net	105	200
Other income	340	145
Loss before income taxes	(112,571)	(66,427)
Income tax expense	485	21
Net loss	$ (113,056)	$ (66,448)
Net loss per common share, basic and diluted	$ (0.70)	$ (0.42)
Weighted average common shares outstanding, basic and diluted	161,231	160,011

[1] Includes the following stock-based compensation expense

Cost of product sales, license fees and royalties	$ 323	$ 163
Research and development	$ 5,464	$ 4,830
Selling, general and administrative	$ 9,176	$ 8,191

ACADIA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	March 31, 2022	**December 31, 2021**

(unaudited)

Assets		
Cash, cash equivalents and investment securities	$ 445,977	$ 520,706
Accounts receivable, net	62,713	64,366
Interest and other receivables	769	978
Inventory	7,009	7,881
Prepaid expenses	25,755	23,892
Total current assets	542,223	617,823
Property and equipment, net	7,531	8,047
Operating lease right-of-use assets	58,186	58,268
Restricted cash	5,770	5,770
Long-term inventory	6,205	6,217
Other assets	4,336	3,997
Total assets	$ 624,251	$ 700,122
Liabilities and stockholders' equity		
Accounts payable	$ 10,768	$ 6,876
Accrued liabilities	108,835	89,192
Total current liabilities	119,603	96,068
Operating lease liabilities	55,478	56,126
Other long-term liabilities	4,373	7,034
Total liabilities	179,454	159,228
Total stockholders' equity	444,797	540,894
Total liabilities and stockholders' equity	$ 624,251	$ 700,122

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