Acadia Pharmaceuticals Reports First Quarter 2024 Financial Results and Operating Overview

May 8, 2024

- First quarter NUPLAZID® (pimavanserin) net product sales of $129.9 million

- First quarter DAYBUE ™ (trofinetide) net product sales of $75.9 million

SAN DIEGO--(BUSINESS WIRE)--May 8, 2024-- Acadia Pharmaceuticals Inc. (Nasdaq: ACAD) today announced its financial results for the first quarter ended March 31, 2024.

“In the first quarter of 2024, Acadia delivered net product sales of $205.8 million, representing 74% revenue growth year over year, primarily due to the addition of our second commercial product, DAYBUE for the treatment of Rett syndrome, combined with growth in market share of NUPLAZID for the treatment of Parkinson’s disease psychosis,” said Steve Davis, Chief Executive Officer. “In addition, we are executing on our plans to bring DAYBUE to markets outside the U.S., continuing to enroll our late-stage trials in Prader-Willi syndrome and Alzheimer’s disease psychosis, and utilizing our financial strength to support our early-stage pipeline and business development opportunities.”

Company Updates

- Seven posters accepted for presentation at the International Rett Syndrome Foundation’s Scientific Meeting to be held on June 18-19, 2024. These will include, among other topics, two encore presentations discussing outcomes from LILAC-2™, as well as findings from exit interviews with caregivers of individuals living with Rett syndrome who participated in the DAYBUE clinical trials supporting its approval. The company will also present a poster with additional real world patient and caregiver experiences from an analysis of an ongoing post marketing observational study.
- The *Journal of Alzheimer’s Disease* published favorable results from a Phase 3b trial evaluating the safety and tolerability of NUPLAZID (pimavanserin) in patients with neuropsychiatric symptoms related to neurodegenerative diseases 60 years of age and older. NUPLAZID was well-tolerated in this elderly, frail population, with a similar rate of treatment-emergent adverse events to the placebo group and did not impact motor or cognitive function versus placebo.
- Appointed Elizabeth H.Z. Thompson, Ph.D. as Executive Vice President, Head of Research and Development. Dr. Thompson joined Acadia’s executive leadership team.

Financial Results

Revenues

Total revenues, comprised of net product sales from NUPLAZID and DAYBUE were $205.8 million for the three months ended March 31, 2024.

Net product sales of NUPLAZID were $129.9 million for the first quarter of 2024, an increase of 10% as compared to $118.5 million for the first quarter of 2023. The increase in net product sales of NUPLAZID was due to 6% sell in growth and a 4% net price benefit in 2024 compared to 2023.

Net product sales of DAYBUE were $75.9 million for the first quarter of 2024. There were no net product sales of DAYBUE in the first quarter of 2023.

Research and Development

Research and development expenses for the first quarter of 2024 were $59.7 million, compared to $69.1 million for the same period of 2023. The decrease in research and development expenses was mainly due to trofinetide commercial supply build that was expensed in the first quarter of 2023, prior to FDA approval. Post-approval inventory expenditures are expensed as part of cost of goods sold.

Selling, General and Administrative

Selling, general and administrative expenses for the first quarter of 2024 were $108.0 million, compared to $101.2 million for the same period of 2023. The increase in selling, general and administrative expenses was primarily driven by annualization of DAYBUE expenses as well as foundational investments to commercialize trofinetide outside the U.S.

Net Income (Loss)

For the first quarter of 2024, Acadia reported net income of $16.6 million, or $0.10 per common share, compared to a net loss of $43.0 million, or $0.27 per common share, for the same period in 2023. Net income for the three months ended March 31, 2024 included $14.8 million of non-cash stock-based compensation expense. Net loss for the three months ended March 31, 2023 included $14.7 million of non-cash stock-based compensation expense.

Cash and Investments

At March 31, 2024, Acadia’s cash, cash equivalents and investment securities totaled $470.5 million, compared to $438.9 million at December 31, 2023.

Full Year 2024 Financial Guidance

Acadia is reiterating all of its 2024 guidance provided on February 27, 2024.

- DAYBUE net product sales guidance in the range of $370 to $420 million.
- NUPLAZID net product sales guidance in the range of $560 to $590 million.
- R&D expense in the range of $305 to $325 million.
- SG&A expense in the range of $455 to $480 million.

Conference Call and Webcast Information

Acadia will host a conference call to discuss the first quarter 2024 results today, Wednesday, May 8, 2024 at 1:30 p.m. PT/4:30 p.m. ET. The conference call will be available on Acadia's website, Acadia.com, under the investors section and will be archived there until June 7, 2024. The conference call may also 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.

About NUPLAZID® (pimavanserin)

Pimavanserin is a selective serotonin inverse agonist and antagonist preferentially targeting 5-HT2A 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.

About DAYBUE ™ (trofinetide)

Trofinetide is a synthetic version of a naturally occurring molecule known as the tripeptide glycine-proline-glutamate (GPE). The mechanism by which trofinetide exerts therapeutic effects in patients with Rett syndrome is unknown. Trofinetide was approved for the treatment of Rett syndrome in adults and pediatric patients 2 years of age and older by the U.S. Food and Drug Administration in March 2023 under the trade name DAYBUE.

About Acadia Pharmaceuticals

Acadia is advancing breakthroughs in neuroscience to elevate life. For 30 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 FDA-approved drug to treat hallucinations and delusions associated with Parkinson's disease psychosis and the first and only FDA-approved drug for the treatment of Rett syndrome. Our clinical-stage development efforts are focused on Prader-Willi syndrome, Alzheimer's disease psychosis and multiple other programs targeting neuropsychiatric symptoms in central nervous system disorders. For more information, visit us at Acadia.com and follow us on LinkedIn and Twitter.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include all statements other than statements of historical fact and can be identified by terms such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions (including the negative thereof) intended to identify forward-looking statements. Forward-looking statements contained in this press release, include, but are not limited to, statements about: (i) our business strategy, objectives and opportunities, including support for our early-stage pipeline and business development opportunities; (ii) plans for, including timing, development and progress of commercialization or regulatory timelines for, NUPLAZID, DAYBUE (both within and outside the U.S.) and our product candidates; (iii) benefits to be derived from and efficacy of our products, including the potential advantages of NUPLAZID and DAYBUE; (iv) the timing and conduct of our clinical trials, including continued enrollment of our clinical trials in Prader-Willi syndrome and Alzheimer's disease psychosis, and the timing and content of our presentations regarding our clinical trials; and (v) our estimates regarding our future financial performance, profitability or capital requirements, including our full year 2024 financial guidance. Forward-looking statements are subject to known and unknown risks, uncertainties, assumptions and other factors that may cause our actual results, performance or achievements to differ materially and adversely from those anticipated or implied by our forward-looking statements. Such risks, uncertainties and other factors include, but are not limited to: our dependency on the continued successful commercialization of NUPLAZID and DAYBUE and our ability to maintain or increase sales of NUPLAZID or DAYBUE; our plans to commercialize DAYBUE outside the U.S.; the costs of our commercialization plans and development programs, and the financial impact or revenues from any commercialization we undertake; our ability to obtain necessary regulatory approvals for our product candidates and, if and when approved, market acceptance of our products; the risks associated with clinical trials and their outcomes, including risks of unsuccessful enrollment and negative or inconsistent results; our dependence on third-party collaborators, clinical research organizations, manufacturers, suppliers and distributors; the impact of competitive products and therapies; our ability to generate or obtain the necessary capital to fund our operations; our ability to grow, equip and train our specialized sales forces; our ability to manage the growth and complexity of our organization; our ability to maintain, protect and enhance our intellectual property; and our ability to continue to stay in compliance with applicable laws and regulations. Given the risks and uncertainties, you should not place undue reliance on these forward-looking statements. For a discussion of these and other risks, uncertainties and other factors that may cause our actual results, performance or achievements to differ, please refer to our quarterly report on Form 10-Q for the quarter ended March 31, 2024 as well as our subsequent filings with the Securities and Exchange Commission from time to time, including our annual report on Form 10-K for the year ended December 31, 2023. The forward-looking statements contained herein are made as of the date hereof, and we undertake no obligation to update them after this date, 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,	
	2024	**2023**
Revenues		
Product sales, net	$ 205,831	$ 118,462
Total revenues	205,831	118,462
Operating expenses		
Cost of product sales [1][2]	22,951	1,667
Research and development [2]	59,679	69,144
Selling, general and administrative [2]	107,991	101,235
Total operating expenses	190,621	172,046
Income (loss) from operations	15,210	(53,584)
Interest income, net	5,506	3,800
Other income	286	4,845
Income (loss) before income taxes	21,002	(44,939)
Income tax expense (benefit)	4,447	(1,918)
Net income (loss)	$ 16,555	$ (43,021)
Earnings (net loss) per share:		
Basic	$ 0.10	$ (0.27)
Diluted	$ 0.10	$ (0.27)
Weighted average common shares outstanding:		
Basic	164,798	162,263
Diluted	166,623	162,263

[1] Includes license fees and royalties

(2) Includes the following stock-based compensation expense

Cost of product sales, license fees and royalties	$ 153	$ 168
Research and development	$ 4,093	$ 3,972
Selling, general and administrative	$ 10,504	$ 10,565

ACADIA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	March 31, 2024	**December 31, 2023**
	(unaudited)	
Assets		
Cash, cash equivalents and investment securities	$ 470,520	$ 438,865
Accounts receivable, net	94,701	98,267
Interest and other receivables	5,378	4,083
Inventory	61,936	35,819
Prepaid expenses	42,761	39,091
Total current assets	675,296	616,125
Property and equipment, net	4,370	4,612
Operating lease right-of-use assets	54,280	51,855
Intangible assets, net	110,204	65,490
Restricted cash	5,770	5,770
Long-term inventory	4,707	4,628
Other assets	476	476
Total assets	$ 855,103	$ 748,956
Liabilities and stockholders' equity		

Accounts payable	$ 19,332	$ 17,543
Accrued liabilities	311,265	236,711
Total current liabilities	330,597	254,254
Operating lease liabilities	49,189	47,800
Other long-term liabilities	11,273	15,147
Total liabilities	391,059	317,201
Total stockholders' equity	464,044	431,755
Total liabilities and stockholders' equity	$ 855,103	$ 748,956

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