Acadia Pharmaceuticals Reports First Quarter 2023 Financial Results and Operating Overview

May 8, 2023

- 1Q23 NUPLAZID® net sales of $118.5 million

- Announced the U.S. FDA Approval of DAYBUE™ (trofinetide) for the Treatment of Rett Syndrome in Adult and Pediatric Patients Two Years of Age and Older on March 10, 2023

- Announced DAYBUE Availability on April 17, 2023

SAN DIEGO--(BUSINESS WIRE)--May 8, 2023-- Acadia Pharmaceuticals Inc. (Nasdaq: ACAD) today announced its financial results for the first quarter ended March 31, 2023.

“We are excited with the recent approval and subsequent launch of DAYBUE, the first and only FDA-approved medicine for the treatment of Rett syndrome. We are executing on our launch strategy to bring this important new treatment to the Rett patient community, while remaining focused on delivering increasing profitability from our NUPLAZID franchise for Parkinson’s disease psychosis,” said Steve Davis, Chief Executive Officer. “In addition to our commercial business, we’ve made important strides in our pipeline including completion of the Phase 1 development program for ACP-204. And finally, we are nearing enrollment completion of the Phase 3 program for pimavanserin as a potential treatment for the negative symptoms of schizophrenia with top-line results expected in early 2024.”

Company Operational, Scientific, and Regulatory Updates

- On March 10, 2023, DAYBUE™ (trofinetide) was approved by the U.S. Food and Drug Administration (FDA) for the treatment of Rett syndrome in adult and pediatric patients two years of age and older.
- In connection with the FDA approval of DAYBUE, Acadia received a Rare Pediatric Disease Priority Review Voucher.
- Announced DAYBUE availability on April 17, 2023.
- The Company expects to complete enrollment in ADVANCE-2, a Phase 3 study evaluating pimavanserin for the treatment of the negative symptoms of schizophrenia, around mid-year with top-line results expected in early 2024.
- ACP-204 has completed Phase 1 development. ACP-204 demonstrated a favorable safety and tolerability profile and we identified the doses we plan to evaluate in Phase 2. The Phase 1 data supports ACP-204’s target product profile as a potential treatment for Alzheimer’s disease psychosis. Acadia plans to meet with the FDA to discuss the clinical development plan.

Financial Results

Revenue

Net sales of NUPLAZID® were $118.5 million for the three months ended March 31, 2023, an increase of 3% as compared to $115.5 million reported for the three months ended March 31, 2022. Year over year demand growth was up approximately 2% in the quarter, driven by an increase in new patient starts across both specialty pharmacy and specialty distribution channels. Overall sell-in volume declined approximately 2% year over year as in-channel inventory declined in the first quarter of 2023 compared to an increase in in-channel inventory in the first quarter of 2022.

Research and Development

Research and development expenses for the three months ended March 31, 2023 were $69.1 million, compared to $128.9 million for the same period of 2022. The decrease was primarily due to a $60 million upfront payment made to Stoke Therapeutics for a license and collaboration agreement in the first quarter of 2022.

Selling, General and Administrative

Selling, general and administrative expenses for the three months ended March 31, 2023 were $101.2 million, compared to $96.7 million for the same period of 2022. Selling, general and administrative expense remained relatively steady year over year as a result of a reduction in spend in the PDP commercial franchise which was offset by investments in the DAYBUE launch.

Net Loss

For the three months ended March 31, 2023, Acadia reported a net loss of $43.0 million, or $0.27 per common share, compared to a net loss of $113.1 million, or $0.70 per common share, for the same period in 2022. The difference was primarily due to the $60 million upfront payment made to Stoke Therapeutics for a license and collaboration agreement. The net losses for the three months ended March 31, 2023 and 2022 included $14.7 million and $15.0 million, respectively, of non-cash stock-based compensation expense.

Cash and Investments

At March 31, 2023, Acadia's cash, cash equivalents, and investment securities totaled $402.9 million, compared to $416.8 million at December 31, 2022.

2023 Financial Guidance

Acadia is reiterating all of its 2023 guidance provided on February 27, 2023.

- NUPLAZID net sales in the range of $520 to $550 million.
- R&D expense in the range of $235 to $255 million, which includes approximately $20 million of stock-based compensation expense.
- SG&A expense in the range of $360 to $380 million, which includes approximately $45 million of stock-based compensation expense.

Conference Call and Webcast Information

The conference call will be available on Acadia's website, www.acadia.com under the investors section and will be archived there until June 7, 2023. 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-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 as a potential treatment for the negative symptoms of schizophrenia.

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. In animal studies, trofinetide has been shown to increase branching of dendrites and synaptic plasticity signals. [1,2] More information can be found at DAYBUE.com.

About Acadia Pharmaceuticals

Acadia is advancing breakthroughs in neuroscience to elevate life. For almost 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 approved therapies for hallucinations and delusions associated with Parkinson's disease psychosis and for the treatment of Rett syndrome. Our clinical-stage development efforts are focused on treating the negative symptoms of schizophrenia, Alzheimer's disease psychosis 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 regarding the timing of future events. 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 risks and uncertainties inherent in drug development, approval and commercialization. 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, 2022 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.

References

[1] Tropea D, Giacometti E, Wilson NR, et al. Partial reversal of Rett Syndrome-like symptoms in MeCP2 mutant mice. *Proc Natl Acad Sci USA*. 2009;106(6):2029-2034.

[2] Acadia Pharmaceuticals Inc., Data on file. Study Report 2566-026. 2010.

ACADIA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

(Unaudited)

	Three Months Ended March 31,	
	2023	2022
Revenues		
Product sales, net	$ 118,462	$ 115,468
Total revenues	118,462	115,468
Operating expenses		
Cost of product sales, license fees and royalties [1]	1,667	2,950
Research and development [1]	69,144	128,855
Selling, general and administrative [1]	101,235	96,679
Total operating expenses	172,046	228,484
Loss from operations	(53,584)	(113,016)
Interest income, net	3,800	105
Other income	4,845	340
Loss before income taxes	(44,939)	(112,571)
Income tax (benefit) expense	(1,918)	485
Net loss	$ (43,021)	$ (113,056)
Net loss per common share, basic and diluted	$ (0.27)	$ (0.70)
Weighted average common shares outstanding, basic and diluted	162,263	161,231

[1] Includes the following stock-based compensation expense

Cost of product sales, license fees and royalties	$ 168	$ 323
Research and development	$ 3,972	$ 5,464
Selling, general and administrative	$ 10,565	$ 9,176

ACADIA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	March 31, 2023	December 31, 2022
	(unaudited)	
Assets		
Cash, cash equivalents and investment securities	$ 402,873	$ 416,823
Accounts receivable, net	65,915	62,195
Interest and other receivables	4,335	885
Inventory	6,095	6,636
Prepaid expenses	23,632	21,398
Total current assets	502,850	507,937
Property and equipment, net	5,595	6,021
Operating lease right-of-use assets	54,151	55,573
Intangible assets, net	69,583	—
Restricted cash	5,770	5,770
Long-term inventory	4,924	4,924
Other assets	12,432	7,587
Total assets	$ 655,305	$ 587,812
Liabilities and stockholders' equity		
Accounts payable	$ 17,422	$ 12,746
Accrued liabilities	206,879	112,884
Total current liabilities	224,301	125,630
Operating lease liabilities	51,441	52,695
Other long-term liabilities	5,305	9,074
Total liabilities	281,047	187,399
Total stockholders' equity	374,258	400,413
Total liabilities and stockholders' equity	$ 655,305	$ 587,812

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