Acadia Pharmaceuticals Reports Third Quarter 2024 Financial Results and Operating Overview

November 6, 2024

- 3Q24 total revenues of $250.4 million, up 18% year-over-year

- 3Q24 NUPLAZID® (pimavanserin) net product sales of $159.2 million, up 10% year-over-year

- 3Q24 DAYBUE ™ (trofinetide) net product sales of $91.2 million, up 36% year-over-year

SAN DIEGO--(BUSINESS WIRE)--Nov. 6, 2024-- Acadia Pharmaceuticals Inc. (Nasdaq: ACAD) today announced its financial results for the third quarter ended September 30, 2024.

“The success of Acadia’s two growing commercial franchises is clearly reflected in our third quarter 2024 results, where we delivered $250.4 million in total revenues, putting us on track to reach an impressive milestone of more than $1 billion in annualized sales in 2025,” said Catherine Owen Adams, Chief Executive Officer. “In my new role as CEO, I’m inspired and excited by the possibilities that lie ahead for Acadia, both with our current portfolio and the exciting innovations in our pipeline. The opportunity to deliver additional groundbreaking therapies to patients who need them is truly compelling. Furthermore, I see significant potential to enhance shareholder value as we continue to execute our commercial priorities and advance our pipeline assets.”

Company Updates

- In August, world-renowned actor/entrepreneur and Parkinson’s disease advocate Ryan Reynolds announced with the Company the launch of a multi-faceted disease education campaign, ***More to Parkinson’s*** ®, to raise awareness among caregivers, patients and their care providers about a common, yet under-recognized aspect of Parkinson’s disease – Parkinson’s-related hallucinations and delusions.
- Advancing the science in Parkinson’s disease with data presentations at the International Congress of Parkinson’s Disease and Movement Disorders Society in October on the topics of sleep improvements and the value of early treatment of Parkinson’s disease psychosis with pimavanserin versus treating later in disease progression.
- In October, Health Canada granted marketing authorization of DAYBUE (trofinetide) for the treatment of Rett syndrome in adult and pediatric patients two years of age and older under its Priority Review process. The Notice of Compliance authorization of DAYBUE makes it the first and only drug approved in Canada for the treatment of Rett syndrome.
- In November, the Company announced it entered into a definitive asset purchase agreement to sell its Rare Pediatric Disease Priority Review Voucher (PRV) for $150 million, following the closing of the sale. Pursuant to the license agreement, Acadia is required to pay Neuren Pharmaceuticals Limited one-third of the net proceeds received from the sale of the PRV.

Financial Results

Revenues

Net product sales of NUPLAZID were $159.2 million and $144.8 million for the three months ended September 30, 2024 and 2023, respectively. The 10% year-over-year increase in net product sales of NUPLAZID included 7% volume growth in 2024 compared to 2023. Net product sales of NUPLAZID were $446.5 million and $405.3 million for the nine months ended September 30, 2024 and 2023, respectively.

Net product sales of DAYBUE were $91.2 million and $66.9 million for the three months ended September 30, 2024 and 2023, respectively. Net product sales of DAYBUE were $251.7 million and $90.1 million for the nine months ended September 30, 2024 and 2023, respectively. The increase in net product sales of DAYBUE for both periods was primarily due to the growth in unit sales.

Research and Development

Research and development expenses were $66.6 million, compared to $157.0 million for the three months ended September 30, 2024 and 2023, respectively. The decrease was mainly due to decreased business development payments, which in the period ending September 30, 2023 included the $100.0 million payment to Neuren under the license agreement for trofinetide. For the nine months ended September 30, 2024 and 2023, research and development expenses were $202.5 million and $284.9 million, respectively. The decrease was mainly due to the aforementioned payment, partially offset by increased costs from clinical stage programs.

Selling, General and Administrative

Selling, general and administrative expenses were $133.3 million and $97.9 million for the three months ended September 30, 2024 and 2023, respectively. For the nine months ended September 30, 2024 and 2023, selling, general and administrative expenses were $358.3 million and $295.1 million, respectively. The increase for this period was primarily driven by the costs related to the consumer activation program to support the NUPLAZID franchise, increased marketing costs in the U.S. to support DAYBUE and investments to support commercialization of DAYBUE outside the U.S.

Net Income (Loss)

For the three months ended September 30, 2024, Acadia reported net income of $32.8 million, or $0.20 per common share, compared to net loss of $65.2 million, or $0.40 per common share, for the same period in 2023. Net income for the three months ended September 30, 2024 included $26.2 million of non-cash stock-based compensation expense. Net loss for the three months ended September 30, 2023 included $18.5 million of non-cash stock-based compensation expense. For the nine months ended September 30, 2024, Acadia reported net income of $82.7 million, or $0.50 per common share, compared to a net loss of $107.1 million, or $0.65 per common share. Net income for the nine months ended September 30, 2024 included $56.6 million of non-cash stock-based compensation expense. Net loss for the nine months ended September 30, 2023 included $48.4 million of non-cash stock-based compensation expense.

Cash and Investments

At September 30, 2024, Acadia's cash, cash equivalents and investment securities totaled $565.3 million, compared to $438.9 million at December 31, 2023.

Full Year 2024 Financial Guidance

Acadia is updating its 2024 guidance:

- NUPLAZID net product sales guidance is narrowed to the high end of the prior range and is now expected to be $600 to $610 million.
- DAYBUE net product sales guidance is narrowed to the low end of the prior range and is now expected to be $340 to $350 million.
- Total revenue guidance is revised to a range of $940 to $960 million.
- R&D expense guidance is lowered and is now expected to be between $280 to $290 million.
- SG&A expense guidance is increased and is now expected to be between $480 to $495 million.

Conference Call and Webcast Information

Acadia will host a conference call to discuss the third quarter 2024 results today, Wednesday, November 6, 2024 at 1:30 p.m. PT/4:30 p.m. ET. 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.

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. Since our founding 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 approved drug in the United States and Canada 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 X.

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," "continue" 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 and innovations in our pipeline assets and business development opportunities, and potential for enhanced shareholder value; (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; (v) our estimates regarding our future financial performance, profitability or capital requirements, including our full year 2024 financial guidance and potential achievement of our milestone of annualized sales in 2025; and (vi) the closing of the sale of the PRV, receipt of payment for the PRV in connection with the closing, HSR clearance of the sale and the anticipated use of proceeds from the sale of the PRV. 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., including in Canada; the costs of our commercialization plans and development programs, and the financial impact or revenues from any commercialization we undertake; our ability to satisfy or waive all required closing conditions for the sale of the PRV and ultimately close the PRV sale;

our ability to obtain HSR clearance in a timely manner or at all; our ability to successfully deploy the proceeds of the PRV sale as anticipated; 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 June 30, 2024 as well as our subsequent filings with the Securities and Exchange Commission (SEC) from time to time, including our quarterly report on Form 10-Q for the quarter ended September 30, 2024 being filed with the SEC today, which will be available at www.sec.gov. 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 September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Revenues				
Product sales, net	$ 250,401	$ 211,699	$ 698,195	$ 495,396
Total revenues	250,401	211,699	698,195	495,396
Operating expenses				
Cost of product sales [1][2]	18,857	14,622	60,038	23,747
Research and development [2]	66,606	156,963	202,518	284,878
Selling, general and administrative [2]	133,294	97,890	358,348	295,094
Total operating expenses	218,757	269,475	620,904	603,719
Income (loss) from operations	31,644	(57,776)	77,291	(108,323)
Interest income, net	6,586	4,125	18,451	12,475
Other income (loss)	576	1,508	1,248	5,109
Income (loss) before income taxes	38,806	(52,143)	96,990	(90,739)
Income tax expense	6,041	13,033	14,281	16,344
Net income (loss)	$ 32,765	$ (65,176)	$ 82,709	$ (107,083)
Earnings (net loss) per share:				
Basic	$ 0.20	$ (0.40)	$ 0.50	$ (0.65)

Diluted	$ 0.20	$ (0.40)	$ 0.50	$ (0.65)
Weighted average common shares outstanding:				
Basic	165,974	164,234	165,443	163,488
Diluted	166,178	164,234	166,136	163,488

(1) Includes license fees and royalties

(2) Includes the following stock-based compensation expense

Cost of product sales, license fees and royalties	$ 383	$ 276	$ 898	$ 644
Research and development	$ 3,863	$ 5,063	$ 11,705	$ 12,701
Selling, general and administrative	$ 21,918	$ 13,200	$ 43,996	$ 35,053

ACADIA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	September 30, 2024	**December 31, 2023**
	(unaudited)	
Assets		
Cash, cash equivalents and investment securities	$ 565,330	$ 438,865
Accounts receivable, net	98,209	98,267
Interest and other receivables	12,154	4,083
Inventory	61,041	35,819
Prepaid expenses	51,550	39,091
Total current assets	788,284	616,125
Property and equipment, net	3,988	4,612
Operating lease right-of-use assets	44,253	51,855

Intangible assets, net	105,515	65,490
Restricted cash	8,770	5,770
Long-term inventory	25,699	4,628
Other assets	359	476
Total assets	$ 976,868	$ 748,956
Liabilities and stockholders' equity		
Accounts payable	$ 19,081	$ 17,543
Accrued liabilities	324,864	236,711
Total current liabilities	343,945	254,254
Operating lease liabilities	40,421	47,800
Other long-term liabilities	15,322	15,147
Total liabilities	399,688	317,201
Total stockholders' equity	577,180	431,755
Total liabilities and stockholders' equity	$ 976,868	$ 748,956

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