Acadia Pharmaceuticals Reports Second Quarter 2023 Financial Results and Operating Overview

August 2, 2023

- 2Q23 DAYBUE ™ (trofinetide) net product sales of $23.2 million

- 2Q23 NUPLAZID® (pimavanserin) net product sales of $142.0 million

- Expanded licensing agreement for trofinetide includes ex-North American rights

SAN DIEGO--(BUSINESS WIRE)--Aug. 2, 2023-- Acadia Pharmaceuticals Inc. (Nasdaq: ACAD) today announced its financial results for the second quarter ended June 30, 2023.

“Our second quarter 2023 results reflect strong performances from both commercial franchises. The DAYBUE launch is off to a highly successful start as evidenced by broad demand across the entire Rett community, and our NUPLAZID franchise is increasingly profitable while continuing to gain market share,” said Steve Davis, President and Chief Executive Officer. “In our late-stage portfolio, we have completed enrollment in our Phase 3 negative symptoms of schizophrenia clinical trial, with results on track for the first quarter of next year. In the fourth quarter of this year, we will initiate a Phase 3 trial of ACP-101 for Prader-Willi syndrome, and commence a seamless Phase 2 and 3 program to study ACP-204 in Alzheimer’s disease psychosis.”

Company Updates

- Acquired global rights to trofinetide (DAYBUE) through an expanded agreement with Neuren Pharmaceuticals. The expanded agreement follows the company’s April 2023 U.S. launch of DAYBUE as the first and only drug approved for the treatment of Rett syndrome.
- Completed enrollment in ADVANCE-2, a Phase 3 study evaluating pimavanserin for the treatment of the negative symptoms of schizophrenia, with top-line results expected in the first quarter of 2024.
- Announced the addition of ACP-101, a Phase 3 development candidate to its rare disease portfolio for the treatment of hyperphagia in Prader-Willi syndrome (PWS). The Company recently aligned on plans with the FDA to initiate a Phase 3 study in the fourth quarter of 2023.
- Completed Phase 1 development of ACP-204 which demonstrated a favorable safety and tolerability profile, and supports Acadia's target product profile as a potential treatment for Alzheimer’s disease psychosis. Acadia met with the FDA and aligned on dosing and plans to initiate a Phase 2/3 program in the fourth quarter of 2023.
- Pivotal results from the Phase 3 LAVENDER ™ study evaluating DAYBUE (trofinetide) efficacy and safety in patients with Rett syndrome were published in *Nature Medicine*, demonstrating DAYBUE’s ability to modify the core symptoms of Rett syndrome, which provided the basis for its FDA approval.
- Initiated patient enrollment in the real world evidence Lotus study, a two-year, prospective, online observational study of participants prescribed DAYBUE.
- Announced the appointment of Dr. Kevin R. Oliver as Senior Vice President, Chief Business Officer to oversee all business development functions and partnering activities.

Financial Results

Revenue

Total net product sales, comprised of NUPLAZID and DAYBUE were $165.2 million for the three months ended June 30, 2023, and were $283.7 million for the six months ended June 30, 2023.

Net product sales of NUPLAZID were $142.0 million and $134.6 million for the three months ended June 30, 2023 and 2022, respectively. The increase in net product sales of NUPLAZID was primarily due to an increase in volume due to demand from new patient starts of NUPLAZID and a higher average net selling price. Net product sales of NUPLAZID were $260.5 million and $250.0 million for the six months ended June 30, 2023 and 2022. The increase in net product sales of NUPLAZID was a result of similar demand and price dynamics, partially offset by a moderate reduction of in-channel inventory.

Net product sales of DAYBUE were $23.2 million for the quarter ended June 30, 2023, the first quarter of commercialization of DAYBUE following the launch of DAYBUE on April 17, 2023.

Research and Development

Research and development expenses for the three months ended June 30, 2023 were $58.8 million, compared to $75.6 million for the same period of 2022. The decrease in research and development expenses was mainly due to decreased costs in the prior year associated with pre-approval manufacturing supply expenses for trofinetide. For the six months ended June 30, 2023 and 2022, research and development expenses were $127.9 million and $204.5 million, respectively. The decrease was primarily due to a $60.0 million upfront payment made to Stoke Therapeutics for a license and collaboration agreement in the first quarter of 2022 as well as a reduction in overall program spend.

Selling, General and Administrative

Selling, general and administrative expenses for the three months ended June 30, 2023 were $96.0 million, compared to $89.9 million for the same period of 2022. For the six months ended June 30, 2023 and 2022, selling, general and administrative expenses were $197.2 million and $186.6 million, respectively. The increase in selling, general and administrative expenses in both periods was primarily due to increased commercial costs associated with the DAYBUE launch, partially offset by efficiencies in our commercial support of NUPLAZID.

Net Income

For the three months ended June 30, 2023, Acadia reported net income of $1.1 million, or $0.01 per common share, compared to a net loss of $34.0 million, or $0.21 per common share, for the same period in 2022. The net income and loss for the three months ended June 30, 2023 and 2022 included $15.2 million and $20.5 million, respectively, of non-cash stock-based compensation expense. For the six months ended June 30, 2023, Acadia reported a net loss of $41.9 million, or $0.26 per common share, compared to a net loss of $147.1 million, or $0.91 per common share, for the same period in 2022. The net losses for the six months ended June 30, 2023 and 2022 included $29.9 million and $35.5 million, respectively, of non-cash stock-based compensation expense.

Cash and Investments

At June 30, 2023, Acadia's cash, cash equivalents and investment securities totaled $375.4 million, compared to $416.8 million at December 31, 2022.

Financial Guidance

Third Quarter 2023

- DAYBUE third quarter net sales in the range of $45 to $55 million.

Full Year 2023

- NUPLAZID full year net sales in the range of $530 to $545 million.
- R&D expense in the range of $335 to $355 million, which has been adjusted for the $100.0 million upfront payment to Neuren in July for the expanded licensing agreement.
- SG&A expense range increased to $380 to $400 million due to higher operating costs as a result of favorable business performance, including employee retention costs as well as DAYBUE incentive compensation and investments in patient support services.

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 September 1, 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-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. 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]

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 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, Prader-Willi syndrome, 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 June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Revenues				
Product sales, net	$ 165,235	$ 134,563	$ 283,697	$ 250,031
Total revenues	165,235	134,563	283,697	250,031
Operating expenses				
Cost of product sales [(1)(2)]	7,459	2,667	9,126	5,617
Research and development [(2)]	58,771	75,646	127,915	204,501
Selling, general and administrative [(2)]	95,968	89,901	197,203	186,580
Total operating expenses	162,198	168,214	334,244	396,698
Income (loss) from operations	3,037	(33,651)	(50,547)	(146,667)
Interest income, net	4,550	580	8,350	685
Other (loss) income	(1,244)	(497)	3,601	(157)
Income (loss) before income taxes	6,343	(33,568)	(38,596)	(146,139)
Income tax (benefit) expense	5,229	443	3,311	928
Net income (loss)	$ 1,114	$ (34,011)	$ (41,907)	$ (147,067)
Earnings (net loss) per share:				
Basic	$ 0.01	$ (0.21)	$ (0.26)	$ (0.91)
Diluted	$ 0.01	$ (0.21)	$ (0.26)	$ (0.91)
Weighted average common shares outstanding:				
Basic	163,458	161,654	163,109	161,443

Diluted	165,046	161,654	163,109	161,443

(1) Includes license fees and royalties

(2) Includes the following stock-based compensation expense

Cost of product sales, license fees and royalties	$ 200	$ 346	$ 368	$ 669
Research and development	$ 3,666	$ 7,232	$ 7,638	$ 12,696
Selling, general and administrative	$ 11,288	$ 12,934	$ 21,853	$ 22,110

ACADIA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	June 30, 2023	**December 31, 2022**
	(unaudited)	
Assets		
Cash, cash equivalents and investment securities	$ 375,378	$ 416,823
Accounts receivable, net	81,852	62,195
Interest and other receivables	2,304	885
Inventory	9,199	6,636
Prepaid expenses	23,895	21,398
Total current assets	492,628	507,937
Property and equipment, net	5,193	6,021
Operating lease right-of-use assets	52,382	55,573
Intangible assets, net	68,219	—
Restricted cash	8,120	5,770
Long-term inventory	4,924	4,924

Other assets	11,303	7,587
Total assets	$ 642,769	$ 587,812
Liabilities and stockholders' equity		
Accounts payable	$ 18,811	$ 12,746
Accrued liabilities	169,131	112,884
Total current liabilities	187,942	125,630
Operating lease liabilities	49,778	52,695
Other long-term liabilities	9,256	9,074
Total liabilities	246,976	187,399
Total stockholders' equity	395,793	400,413
Total liabilities and stockholders' equity	$ 642,769	$ 587,812

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Source: Acadia Pharmaceuticals Inc.