
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 27, 2024

Acadia Pharmaceuticals Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

000-50768
(Commission File Number)

06-1376651
(IRS Employer
Identification No.)

12830 El Camino Real, Suite 400
San Diego, California
(Address of Principal Executive Offices)

92130
(Zip Code)

Registrant's Telephone Number, Including Area Code: (858) 558-2871

N/A

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	ACAD	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On February 27, 2024, Acadia Pharmaceuticals Inc. issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2023. A copy of this press release is furnished herewith as Exhibit 99.1. Pursuant to the rules and regulations of the Securities and Exchange Commission, such exhibit and the information set forth therein and in this Item 2.02 have been furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to liability under that section nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing regardless of any general incorporation language.

Item 9.01 Financial Statements and Exhibits.**(d) Exhibits.**

Exhibit Number	Description
99.1	Press Release dated February 27, 2024.
104	Cover page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Acadia Pharmaceuticals Inc.

Date: February 27, 2024

By: /s/ Jennifer J. Rhodes

Jennifer J. Rhodes

Executive Vice President, Chief Legal Officer

Acadia Pharmaceuticals Reports Fourth Quarter and Full Year 2023 Financial Results and Operating Overview

- 2023 total net product sales of \$726.4 million, reflecting 40% revenue growth.

- Fourth quarter DAYBUE™ (trofinetide) net product sales of \$87.1 million and full year 2023 net product sales of \$177.2 million.

- Fourth quarter NUPLAZID® (pimavanserin) net product sales of \$143.9 million and full year 2023 net product sales of \$549.2 million.

SAN DIEGO, CA, February 27, 2024 – Acadia Pharmaceuticals Inc. (Nasdaq: ACAD), today announced its financial results for the fourth quarter and full year ended December 31, 2023.

“2023 was a transformational year for Acadia that positioned us for continued success in 2024 and beyond. We achieved 40% revenue growth primarily driven by the launch of our second commercial product, DAYBUE for the treatment of Rett syndrome, in addition to 6% growth in our established NUPLAZID franchise,” said Steve Davis, Chief Executive Officer. “In the fourth quarter we significantly advanced our pipeline with the initiation of a Phase 3 trial of ACP-101 in Prader-Willi syndrome, as well as our seamless Phase 2 / Phase 3 program for ACP-204 in Alzheimer’s disease psychosis. We look forward to announcing top-line results from our ADVANCE-2 study of pimavanserin for the negative symptoms of schizophrenia by the end of the first quarter.”

Company Updates

- Anticipated to report top-line results from ADVANCE-2, a Phase 3 study evaluating pimavanserin for the treatment of the negative symptoms of schizophrenia by the end of the first quarter.
- Initiated a pivotal Phase 3 COMPASS PWS study of ACP-101 (intranasal carbetocin) for the treatment of hyperphagia in Prader-Willi syndrome in the fourth quarter of 2023.
- Initiated a Phase 2 clinical trial of ACP-204 for the treatment of Alzheimer’s disease psychosis in the fourth quarter of 2023.
- Appointed Jennifer J. Rhodes as Executive Vice President, Chief Legal Officer and Secretary, and Kimberly J. Manhard as Senior Vice President, Global Strategic Planning and Execution. Jennifer and Kimberly both joined Acadia’s executive leadership team.

Financial Results*Revenues*

Total revenues, comprised of net product sales from NUPLAZID and DAYBUE, were \$231.0 million for the fourth quarter of 2023 and \$726.4 million for the full year 2023.

Net product sales of NUPLAZID were \$143.9 million for the fourth quarter of 2023, an increase of 5% as compared to \$136.5 million for the fourth quarter of 2022. Net product sales of NUPLAZID were \$549.2 million for the full year 2023, an increase of 6% as compared to \$517.2 million for the full year 2022. The increase in net product sales of NUPLAZID was due to growth in unit sales and a higher average net selling price in 2023 compared to 2022.

Net product sales of DAYBUE were \$87.1 million for the fourth quarter of 2023 and \$177.2 million for the full year 2023. During 2022, there were no net product sales of DAYBUE, which was launched in April 2023.

Research and Development

Research and development expenses for the fourth quarter of 2023 were \$66.7 million, compared to \$75.7 million for the same period of 2022. For the full years of 2023 and 2022, research and development expenses were \$351.6 million and \$361.6 million, respectively. The decrease in research and development expenses during 2023 was mainly due to trofinetide commercial supply build that was expensed prior to approval. There was a similar level of clinical spend and business development investment year over year.

Selling, General and Administrative

Selling, general and administrative expenses for the fourth quarter of 2023 were \$111.5 million, compared to \$104.4 million for the same period of 2022. For the full years of 2023 and 2022, selling, general and administrative expenses were \$406.6 million and \$369.1 million, respectively. The increase in selling, general and administrative expenses was primarily due to increased commercial costs associated with the DAYBUE launch, partially offset by reductions in expenses associated with NUPLAZID.

Net Income (Loss)

For the fourth quarter of 2023, Acadia reported net income of \$45.8 million, or \$0.28 per common share, compared to a net loss of \$41.7 million, or \$0.26 per common share, for the same period in 2022. The net income and loss for the fourth quarters of 2023 and 2022 included \$18.0 million and \$14.4 million, respectively, of non-cash stock-based compensation expense. For the full year 2023, Acadia reported a net loss of \$61.3 million, or \$0.37 per common share, compared to a net loss of \$216.0 million, or \$1.34 per common share, for the same period in 2022. The net losses for the full years of 2023 and 2022 included \$66.4 million and \$68.2 million, respectively, of non-cash stock-based compensation expense.

Cash and Investments

At December 31, 2023, Acadia's cash, cash equivalents, and investment securities totaled \$438.9 million, compared to \$416.8 million at December 31, 2022.

Full Year 2024 Financial Guidance

- DAYBUE net product sales in the range of \$370 to \$420 million.
- NUPLAZID net product sales in the range of \$560 to \$590 million.
- GAAP R&D expense in the range of \$305 to \$325 million.
- GAAP 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 fourth quarter and full year December 31, 2023 results today, Tuesday, February 27, 2024 at 1:30 p.m. PT/4:30 p.m. ET. The conference call will be available on Acadia's website, www.acadia.com, under the investors section and will be archived there until March 26, 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-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. 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 treating the negative symptoms of schizophrenia, 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 www.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; (ii) plans for, including timing, development and progress of commercialization or regulatory timelines for, NUPLAZID, DAYBUE and our product candidates; (iii) benefits to be derived from and efficacy of our products, including the potential advantages of NUPLAZID and DAYBUE; and (iv) our estimates regarding our future financial performance, profitability or capital requirements. 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; 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; 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 September 30, 2023 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 December 31,		Years Ended December 31,	
	2023	2022	2023	2022
Revenues				
Product sales, net	\$ 231,041	\$ 136,490	\$ 726,437	\$ 517,235
Total revenues	231,041	136,490	726,437	517,235
Operating expenses				
Cost of product sales ⁽¹⁾⁽²⁾	17,891	2,413	41,638	10,166
Research and development ⁽²⁾	66,741	75,738	351,619	361,575
Selling, general and administrative ⁽²⁾	111,465	104,402	406,559	369,090
Total operating expenses	196,097	182,553	799,816	740,831
Income (loss) from operations	34,944	(46,063)	(73,379)	(223,596)
Interest income, net	4,759	3,630	17,234	6,610
Other income	—	1,543	5,109	3,542
Income (loss) before income taxes	39,703	(40,890)	(51,036)	(213,444)
Income tax expense (benefit)	(6,094)	835	10,250	2,531
Net income (loss)	\$ 45,797	\$ (41,725)	\$ (61,286)	\$ (215,975)
Earnings (net loss) per share:				
Basic	\$ 0.28	\$ (0.26)	\$ (0.37)	\$ (1.34)
Diluted	\$ 0.28	\$ (0.26)	\$ (0.37)	\$ (1.34)
Weighted average common shares outstanding:				
Basic	164,812	161,988	163,819	161,683
Diluted	166,510	161,988	163,819	161,683

⁽¹⁾ Includes license fees and royalties

⁽²⁾ Includes the following share-based compensation expenses

Cost of product sales, license fees and royalties	\$ 363	\$ 93	\$ 1,007	\$ 1,106
Research and development	\$ 4,707	\$ 3,432	\$ 17,408	\$ 22,580
Selling, general and administrative	\$ 12,953	\$ 10,889	\$ 48,006	\$ 44,515

ACADIA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	<u>December 31, 2023</u>	<u>December 31, 2022</u>
Assets		
Cash, cash equivalents and investment securities	\$ 438,865	\$ 416,823
Accounts receivable, net	98,267	62,195
Interest and other receivables	4,083	885
Inventory	35,819	6,636
Prepaid expenses	39,091	21,398
Total current assets	<u>616,125</u>	<u>507,937</u>
Property and equipment, net	4,612	6,021
Operating lease right-of-use assets	51,855	55,573
Intangible assets, net	65,490	—
Restricted cash	5,770	5,770
Long-term inventory	4,628	4,924
Other assets	476	7,587
Total assets	<u>\$ 748,956</u>	<u>\$ 587,812</u>
Liabilities and stockholders' equity		
Accounts payable	\$ 17,543	\$ 12,746
Accrued liabilities	236,711	112,884
Total current liabilities	<u>254,254</u>	<u>125,630</u>
Operating lease liabilities	47,800	52,695
Other long-term liabilities	15,147	9,074
Total liabilities	<u>317,201</u>	<u>187,399</u>
Total stockholders' equity	<u>431,755</u>	<u>400,413</u>
Total liabilities and stockholders' equity	<u>\$ 748,956</u>	<u>\$ 587,812</u>

Media Contact:

Acadia Pharmaceuticals Inc.
Deb Kazenelson
(818) 395-3043
media@acadia-pharm.com

Investor Contact:

Acadia Pharmaceuticals Inc.
Al Kildani
(858) 261-2872
ir@acadia-pharm.com

Acadia Pharmaceuticals Inc.
Jessica Tieszen
(858) 261-2950
ir@acadia-pharm.com
