

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): August 06, 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 August 6, 2024, Acadia Pharmaceuticals Inc. issued a press release announcing its financial results for the second quarter and six months ended June 30, 2024. 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 August 6, 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: August 6, 2024

By: /s/ Jennifer J. Rhodes

Jennifer J. Rhodes

Executive Vice President, Chief Legal Officer & Secretary

Acadia Pharmaceuticals Reports Second Quarter 2024 Financial Results and Operating Overview

- Second quarter total net product sales of \$242.0 million, up 46% year-over-year

SAN DIEGO, CA, August 6, 2024 – Acadia Pharmaceuticals Inc. (Nasdaq: ACAD) today announced its financial results for the second quarter ended June 30, 2024.

“In the second quarter of 2024, Acadia delivered \$242.0 million in net product sales, highlighted by 11% year-over-year growth in NUPLAZID net sales and 11% sequential growth in DAYBUE net sales,” said Steve Davis, Chief Executive Officer. “Additionally, we are advancing enrollment in our Phase 3 trial in Prader-Willi syndrome and our Phase 2 / Phase 3 program in Alzheimer’s disease psychosis. With two successful commercial products, a strong pipeline of late and early-stage assets and a growing cash balance, Acadia is in a strong position to support our long-term growth.”

Company Updates

- The journal *Med* published clinical data from two open-label extension studies, LILAC-1 and LILAC-2, which showed that patients treated with DAYBUE™ (trofinetide) who completed these studies experienced improvement in Rett syndrome symptoms as measured by the Rett Syndrome Behaviour Questionnaire (RSBQ).
- Presented interim data from the open-label real-world LOTUS™ study at the 2024 International Rett Syndrome Foundation (IRSF) Annual Scientific Meeting. LOTUS is an ongoing, open-label caregiver-reported study evaluating the efficacy and tolerability outcomes in patients with Rett syndrome treated with DAYBUE.

Financial Results*Revenues*

Total revenues, comprised of net product sales from NUPLAZID® and DAYBUE, were \$242.0 million for the three months ended June 30, 2024, up 46% year-over-year. Total revenues were \$447.8 million for the six months ended June 30, 2024.

Net product sales of NUPLAZID were \$157.4 million and \$142.0 million for the three months ended June 30, 2024 and 2023, respectively. The 11% year-over-year increase in net product sales of NUPLAZID included 6% growth in unit sales in 2024 compared to 2023. Net product sales of NUPLAZID were \$287.3 million and \$260.5 million for the six months ended June 30, 2024 and 2023, respectively.

Net product sales of DAYBUE were \$84.6 million and \$23.2 million for the three months ended June 30, 2024 and 2023, respectively. Net product sales of DAYBUE were \$160.5 million and \$23.2 million for the six months ended June 30, 2024 and 2023, respectively. The increase in net product sales of DAYBUE was due to the growth in DAYBUE unit sales.

Research and Development

Research and development expenses were \$76.2 million, compared to \$58.8 million for the three months ended June 30, 2024 and 2023, respectively. The increase was mainly due to increased costs from ACP-101, ACP-204 and early-stage programs, partially offset by a reduction in costs associated with our pimavanserin negative symptoms of schizophrenia program. For the six months ended June 30, 2024 and 2023, research and development expenses were \$135.9 million and \$127.9 million, respectively. The increase was mainly due to increased costs from ACP-101, ACP-204 and early stage programs, partially offset by the elimination of pre-FDA approval trofinetide commercial supply expenses that were included

in the previous year, as well as a reduction in costs associated with our pimavanserin negative symptoms of schizophrenia program.

Selling, General and Administrative

Selling, general and administrative expenses were \$117.1 million and \$96.0 million for the three months ended June 30, 2024 and 2023, respectively. For the six months ended June 30, 2024 and 2023, selling, general and administrative expenses were \$225.1 million and \$197.2 million, respectively. The increase in selling, general and administrative expenses in both periods was primarily driven by upfront costs related to a new consumer activation program to support the NUPLAZID franchise, increased marketing costs in the U.S. to support DAYBUE, and investments to support commercialization of trofinetide outside the U.S.

Net Income (Loss)

For the three months ended June 30, 2024, Acadia reported net income of \$33.4 million, or \$0.20 per common share, compared to net income of \$1.1 million, or \$0.01 per common share, for the same period in 2023. Net income for the three months ended June 30, 2024 and 2023 included \$15.7 million and \$15.2, respectively, of non-cash stock-based compensation expense. For the six months ended June 30, 2024, Acadia reported net income of \$49.9 million, or \$0.30 per common share, compared to a net loss of \$41.9 million, or \$0.26 per common share. Net income for the six months ended June 30, 2024 included \$30.4 million of non-cash stock-based compensation expense. Net loss for the six months ended June 30, 2023 included \$29.9 million of non-cash stock-based compensation expense.

Cash and Investments

At June 30, 2024, Acadia's cash, cash equivalents and investment securities totaled \$500.9 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 increased to a range of \$590 to \$610 million from the previous range of \$560 to \$590 million, reflecting stronger underlying demand driving recent higher unit volume.
- DAYBUE net product sales guidance is decreased to a range of \$340 to \$370 million from the previous range of \$370 to \$420 million.
- Total revenue guidance is revised to a range of \$930 to \$980 million from the previous range of \$930 million to \$1.01 billion.
- R&D expense guidance is narrowed to the lower end of the previous range and is now expected to be between \$305 to \$315 million.
- SG&A expense guidance is narrowed to the higher end of the previous range and is now expected to be between \$465 to \$480 million.

Conference Call and Webcast Information

Acadia will host a conference call to discuss the second quarter 2024 results today, Tuesday, August 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-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.

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 (SEC) from time to time, including our quarterly report on Form 10-Q for the quarter ended June 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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenues				
Product sales, net	\$ 241,963	\$ 165,235	\$ 447,794	\$ 283,697
Total revenues	241,963	165,235	447,794	283,697
Operating expenses				
Cost of product sales ⁽¹⁾⁽²⁾	18,230	7,459	41,181	9,126
Research and development ⁽²⁾	76,233	58,771	135,912	127,915
Selling, general and administrative ⁽²⁾	117,063	95,968	225,054	197,203
Total operating expenses	211,526	162,198	402,147	334,244
Income (loss) from operations	30,437	3,037	45,647	(50,547)
Interest income, net	6,359	4,550	11,865	8,350
Other income (loss)	386	(1,244)	672	3,601
Income (loss) before income taxes	37,182	6,343	58,184	(38,596)
Income tax expense	3,793	5,229	8,240	3,311
Net income (loss)	\$ 33,389	\$ 1,114	\$ 49,944	\$ (41,907)
Earnings (net loss) per share:				
Basic	\$ 0.20	\$ 0.01	\$ 0.30	\$ (0.26)
Diluted	\$ 0.20	\$ 0.01	\$ 0.30	\$ (0.26)
Weighted average common shares outstanding:				
Basic	165,551	163,458	165,174	163,109
Diluted	166,174	165,046	166,391	163,109

⁽¹⁾ Includes license fees and royalties

⁽²⁾ Includes the following stock-based compensation expense

Cost of product sales, license fees and royalties	\$ 362	\$ 200	\$ 515	\$ 368
Research and development	\$ 3,749	\$ 3,666	\$ 7,842	\$ 7,638
Selling, general and administrative	\$ 11,574	\$ 11,288	\$ 22,078	\$ 21,853

ACADIA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	June 30, 2024	December 31, 2023
	<u>(unaudited)</u>	
Assets		
Cash, cash equivalents and investment securities	\$ 500,942	\$ 438,865
Accounts receivable, net	103,698	98,267
Interest and other receivables	6,695	4,083
Inventory	71,525	35,819
Prepaid expenses	46,056	39,091
Total current assets	<u>728,916</u>	<u>616,125</u>
Property and equipment, net	4,144	4,612
Operating lease right-of-use assets	52,390	51,855
Intangible assets, net	107,859	65,490
Restricted cash	5,770	5,770
Long-term inventory	14,544	4,628
Other assets	476	476
Total assets	<u>\$ 914,099</u>	<u>\$ 748,956</u>
Liabilities and stockholders' equity		
Accounts payable	\$ 19,882	\$ 17,543
Accrued liabilities	317,969	236,711
Total current liabilities	<u>337,851</u>	<u>254,254</u>
Operating lease liabilities	47,186	47,800
Other long-term liabilities	12,362	15,147
Total liabilities	<u>397,399</u>	<u>317,201</u>
Total stockholders' equity	<u>516,700</u>	<u>431,755</u>
Total liabilities and stockholders' equity	<u>\$ 914,099</u>	<u>\$ 748,956</u>

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

Media Contact:

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