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): November 02, 2023

Acadia Pharmaceuticals Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**000-50768**	**06-1376651**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

12830 El Camino Real, Suite 400	
San Diego, California	**92130**
(Address of Principal Executive Offices)	**(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 November 2, 2023, Acadia Pharmaceuticals Inc. issued a press release announcing its financial results for the third quarter and nine months ended September 30, 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 November 2, 2023.
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: November 2, 2023

By: /s/ Austin D. Kim

Austin D. Kim
Executive Vice President, General Counsel & Secretary

Exhibit 99.1

Acadia Pharmaceuticals Reports Third Quarter 2023 Financial Results and Operating Overview

- Company reports record revenues resulting from strong DAYBUE launch and growth in NUPLAZID franchise

- 3Q23 DAYBUE™ (trofinetide) net product sales of $66.9 million

- 3Q23 NUPLAZID® (pimavanserin) net product sales of $144.8 million

SAN DIEGO, CA, November 2, 2023 – Acadia Pharmaceuticals Inc. (Nasdaq: ACAD) today announced its financial results for the third quarter ended September 30, 2023.

“In the third quarter, Acadia delivered record product revenue, underscoring the continued strong launch of DAYBUE for the treatment of Rett syndrome, and market share growth for the very successful NUPLAZID franchise,” said Steve Davis, President and Chief Executive Officer. “In addition to our strong commercial performance, we continue to add to our late stage pipeline with the planned initiations in the fourth quarter of a Phase 3 study of ACP-101 for Prader-Willi syndrome and a Phase 2 / Phase 3 program of ACP-204 for the treatment of Alzheimer’s disease psychosis.”

Company Highlights

- Acquired global rights to trofinetide (DAYBUE) through an expanded agreement with Neuren Pharmaceuticals.
- The Company expects to report top-line results from ADVANCE-2, a Phase 3 study evaluating pimavanserin for the treatment of the negative symptoms of schizophrenia in the first quarter of 2024.
- The Company plans to initiate a Phase 3 placebo-controlled study of ACP-101 for the treatment of hyperphagia in Prader-Willi syndrome in the fourth quarter of 2023.
- The Company plans to initiate a Phase 2 study of ACP-204 as a potential treatment for Alzheimer’s disease psychosis in the fourth quarter of 2023.
- Appointed Albert Kildani as Senior Vice President, Investor Relations and Corporate Communications, and Stephanie Kim as Senior Vice President, Regulatory Affairs. Albert and Stephanie both join Acadia’s Executive Management Committee.

Financial Results

Revenues
Total revenues, comprised of net product sales from NUPLAZID and DAYBUE were $211.7 million for the three months ended September 30, 2023, and were $495.4 million for the nine months ended September 30, 2023.

Net product sales of NUPLAZID were $144.8 million and $130.7 million for the three months ended September 30, 2023 and 2022, respectively. The approximately $14 million dollar increase year over year is comprised of a $7 million in-channel inventory reduction in the prior year that did not recur this year, $4 million attributable to lower 340B volumes, and $3 million as a result of 2% demand bottle growth. Net product sales of NUPLAZID were $405.3 million and $380.7 million for the nine months ended September 30, 2023 and 2022, respectively.

Net product sales of DAYBUE were $66.9 million for the quarter ended September 30, 2023, the first full quarter of commercialization of DAYBUE following the April 17, 2023 launch.

Research and Development
Research and development expenses for the three months ended September 30, 2023 were $157.0 million, compared to $81.3 million for the same period of 2022. The increase in research and development expenses was mainly due to the July 2023 agreement with Neuren to expand Acadia's license to trofinetide (DAYBUE) from North American to worldwide rights, offset in part by other reductions in research and development. For the nine months ended September 30, 2023 and 2022, research and development expenses were $284.9 million and $285.8 million, respectively.

Selling, General and Administrative
Selling, general and administrative expenses for the three months ended September 30, 2023 were $97.9 million, compared to $78.1 million for the same period of 2022. For the nine months ended September 30, 2023 and 2022, selling, general and administrative expenses were $295.1 million and $264.7 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 reductions in expenses associated with NUPLAZID.

Net Loss
For the three months ended September 30, 2023, Acadia reported a net loss of $65.2 million, or $0.40 per common share, compared to a net loss of $27.2 million, or $0.17 per common share, for the same period in 2022. Net loss for the three months ended September 30, 2023 included the $100 million upfront payment to expand Acadia's license to trofinetide (DAYBUE) from North American to worldwide rights. Net loss for the three months ended September 30, 2023 and 2022 included $18.5 million and $18.3 million, respectively, of non-cash stock-based compensation expense. For the nine months ended September 30, 2023, Acadia reported a net loss of $107.1 million, or $0.65 per common share, compared to a net loss of $174.3 million, or $1.08 per common share, for the same period in 2022. The net losses for the nine months ended September 30, 2023 and 2022 included $48.4 million and $53.8 million, respectively, of non-cash stock-based compensation expense.

Cash and Investments
At September 30, 2023, Acadia's cash, cash equivalents and investment securities totaled $345.9 million, compared to $416.8 million at December 31, 2022. The change in these balances is primarily due to the July 2023 $100 million upfront payment for worldwide rights to trofinetide (DAYBUE) referenced above.

Financial Guidance

Fourth Quarter 2023

- DAYBUE net sales in the range of $80 to $87.5 million.

Full Year 2023

- NUPLAZID net sales in the range of $537.5 to $545 million.
- R&D expense in the range of $340 to $350 million.
- SG&A expense in the range of $390 to $400 million.

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 December 4, 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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenues				
Product sales, net	$ 211,699	$ 130,714	$ 495,396	$ 380,745
Total revenues	211,699	130,714	495,396	380,745
Operating expenses				
Cost of product sales [1][2]	14,622	2,136	23,747	7,753
Research and development [2]	156,963	81,336	284,878	285,837
Selling, general and administrative [2]	97,890	78,108	295,094	264,688
Total operating expenses	269,475	161,580	603,719	558,278
Loss from operations	(57,776)	(30,866)	(108,323)	(177,533)
Interest income, net	4,125	2,295	12,475	2,980
Other income	1,508	2,156	5,109	1,999
Loss before income taxes	(52,143)	(26,415)	(90,739)	(172,554)
Income tax expense	13,033	768	16,344	1,696
Net loss	$ (65,176)	$ (27,183)	$ (107,083)	$ (174,250)
Net loss per common share, basic and diluted	$ (0.40)	$ (0.17)	$ (0.65)	$ (1.08)
Weighted average common shares outstanding, basic and diluted	164,234	161,852	163,488	161,580

[1] Includes license fees and royalties

[2] Includes the following stock-based compensation expense

Cost of product sales, license fees and royalties	$ 276	$ 344	$ 644	$ 1,013
Research and development	$ 5,063	$ 6,452	$ 12,701	$ 19,148
Selling, general and administrative	$ 13,200	$ 11,516	$ 35,053	$ 33,626

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

	September 30, 2023	December 31, 2022
	(unaudited)	
Assets		
Cash, cash equivalents and investment securities	$ 345,920	$ 416,823
Accounts receivable, net	92,802	62,195
Interest and other receivables	1,730	885
Inventory	20,768	6,636
Prepaid expenses	37,950	21,398
Total current assets	499,170	507,937
Property and equipment, net	4,884	6,021
Operating lease right-of-use assets	50,758	55,573
Intangible assets, net	66,855	—
Restricted cash	5,770	5,770
Long-term inventory	4,628	4,924
Other assets	475	7,587
Total assets	$ 632,540	$ 587,812
Liabilities and stockholders' equity		
Accounts payable	$ 12,310	$ 12,746
Accrued liabilities	197,293	112,884
Total current liabilities	209,603	125,630
Operating lease liabilities	48,103	52,695
Other long-term liabilities	12,660	9,074
Total liabilities	270,366	187,399
Total stockholders' equity	362,174	400,413
Total liabilities and stockholders' equity	$ 632,540	$ 587,812

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