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, 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** **(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, 2023, Acadia Pharmaceuticals Inc. issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2022. 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, 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: February 27, 2023

By: /s/ Austin D. Kim

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

Exhibit 99.1

Acadia Pharmaceuticals Reports Fourth Quarter and Full Year 2022 Financial Results and Operating Overview

- Full year 2022 net sales of $517.2 million, an increase of 7% over 2021

- Prescription Drug User Fee Act (PDUFA) action date set for March 12, 2023, for trofinetide for the treatment of Rett syndrome

SAN DIEGO, CA, February 27, 2023 – Acadia Pharmaceuticals Inc. (Nasdaq: ACAD), today announced its financial results for the fourth quarter and full year ended December 31, 2022.

NUPLAZID® delivered net sales of $136.5 million in the fourth quarter of 2022 and $517.2 million for the full year. The improvement was mainly driven by an increase in demand in the long-term care channel and retention of continuing patients across all channels. Overall demand in 2022 was relatively steady compared to the previous year.

“We are poised for a transformative year in 2023. Our increasingly profitable NUPLAZID franchise supports future growth opportunities, including trofinetide - which has the potential to become our second marketed product - as well as the development of our pipeline,” said Steve Davis, Chief Executive Officer. “Last year we submitted our New Drug Application for trofinetide for the treatment of Rett syndrome and we are eager to get to our PDUFA action date of March 12, 2023. Importantly, we also advanced our Phase 3 negative symptoms of schizophrenia program and introduced ACP-204, a new molecule that we plan to evaluate in patients with Alzheimer’s disease psychosis later this year.”

Company Operational, Scientific, and Regulatory Updates

- Trofinetide New Drug Application (NDA) for the treatment of Rett syndrome has an assigned PDUFA action date of March 12, 2023.

- Two large, retrospective analyses of Medicare patients were published in 2022, the first in the *American Journal of Psychiatry*[1] and the second in the journal, *Drug Safety*[2]. Both of these analyses found a lower mortality risk in patients with Parkinson’s disease psychosis (PDP) treated with NUPLAZID (pimavanserin) when compared to other atypical antipsychotics over the first 180 days and first 12 months, respectively.

- Another large, retrospective analysis of Medicare patients recently published in *The Journal of Medical Economics*[3] found health care resource utilization patterns, such as hospitalizations and ER visits, were lower among patients with PDP treated with NUPLAZID (pimavanserin) when compared to other atypical antipsychotics over 12 months.

- Enrollment is expected to be completed for ADVANCE-2, a Phase 3 study evaluating pimavanserin for the negative symptoms of schizophrenia, around mid-year 2023.

- Doug Williamson, M.D., was appointed as Executive Vice President, Head of Research and Development in January 2023. Dr. Williamson succeeded Dr. Srdjan (Serge) Stankovic who retired at the end of 2022.

Financial Results

Revenue
Net sales of NUPLAZID® (pimavanserin) were $136.5 million for the three months ended December 31, 2022, an increase of 4% as compared to $130.8 million reported for the three months ended December 31, 2021. For the years ended December 31, 2022 and 2021, Acadia reported net product sales of $517.2 million and $484.1 million, respectively, an increase of 7% year-over-year.

Research and Development
Research and development expenses for the three months ended December 31, 2022 were $75.7 million, compared to $67.1 million for the same period of 2021. For the years ended December 31, 2022 and 2021, research and development expenses were $361.6 million and $239.4 million, respectively. The increase in research and development expenses during 2022 was primarily related to a $60 million upfront payment for a collaboration with Stoke Therapeutics, a $10 million milestone payment to our partner, Neuren Pharmaceuticals, upon acceptance of the trofinetide NDA filing, as well as increased costs of manufacturing activities for trofinetide, and the development of early-stage programs, including additional business development activity.

Selling, General and Administrative
Selling, general and administrative expenses for the three months ended December 31, 2022 were $104.4 million, compared to $105.8 million for the same period of 2021. For the years ended December 31, 2022 and 2021, selling, general and administrative expenses were $369.1 million and $396.0 million, respectively. The decrease was related to the continued reduction and optimization of commercial spend related to NUPLAZID, leading to a reduction in overall advertising and promotional costs, offset by investments in preparing for the launch of trofinetide.

Net Loss
For the fourth quarter of 2022, Acadia reported a net loss of $41.7 million, or $0.26 per common share, compared to a net loss of $43.1 million, or $0.27 per common share, for the same period in 2021. The net losses for the fourth quarters of 2022 and 2021 included $14.4 million and $12.9 million, respectively, of non-cash stock-based compensation expense. For the year ended December 31, 2022, Acadia reported a net loss of $216.0 million, or $1.34 per common share, compared to a net loss of $167.9 million, or $1.05 per common share, for the same period in 2021. The net losses for the years ended December 31, 2022 and 2021 included $68.2 million and $63.6 million, respectively, of non-cash stock-based compensation expense.

Cash and Investments
At December 31, 2022, Acadia's cash, cash equivalents, and investment securities totaled $416.8 million, compared to $520.7 million at December 31, 2021.

2023 Financial Guidance

For the full year 2023, the Company expects:

- Net NUPLAZID sales in the range of $520 to $550 million.
- On a GAAP basis, R&D expense in the range of $235 to $255 million, which includes approximately $20 million of stock-based compensation expense.
- On a GAAP basis, SG&A expense in the range of $360 to $380 million, which includes approximately $45 million of stock-based compensation expense.

Conference Call and Webcast Information
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. The registration link will also be available on Acadia's website, www.acadia.com under the investors section and will be archived there until April 3, 2023.

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 Acadia Pharmaceuticals
Acadia is advancing breakthroughs in neuroscience to elevate life. For more than 25 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 therapy for hallucinations and delusions associated with Parkinson's disease psychosis. Our clinical-stage development efforts are focused on treating the negative symptoms of schizophrenia, Rett 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.

About Trofinetide
Trofinetide is an investigational drug. It is a synthetic analog of the tripeptide glycine-proline-glutamate (GPE), a product of the naturally occurring cleavage of insulin-like growth factor 1. Trofinetide is thought to enhance neuronal synaptic function and morphology, supporting its potential role in treating Rett syndrome. This hypothesis is supported by findings from studies of GPE and trofinetide in a Mecp2 mouse model of Rett syndrome, in which increased branching of the dendrites that form synapses and synaptic plasticity signals were observed.

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, 2021 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]Mosholder AD, Ma Y, Akhtar S, et al. Mortality among Parkinson's disease patients treated with pimavanserin or atypical antipsychotics: an observational study in Medicare beneficiaries. *Am J Psychiatry*. 2022;179(8):553-561.

[2]Layton JB, Forns J, McQuay LJ, et al. Mortality in patients with Parkinson's disease-related psychosis treated with pimavanserin compared with other atypical antipsychotics: a cohort study. *Drug Safety*. 2023;46(2):195-208.

[3]Rajagopalan K, Rashid N, Kumar S, and Doshi D. Health care resource utilization patterns among patients with Parkinson's disease psychosis: analysis of Medicare beneficiaries treated with Pimavanserin or other-atypical antipsychotics. *J Med Econ*. 2023;26(1):34-42.

ACADIA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)
(Unaudited)

	Three Months Ended December 31,		Years Ended December 31,	
	2022	2021	2022	2021
Revenues				
Product sales, net	$ 136,490	$ 130,758	$ 517,235	$ 484,145
Total revenues	136,490	130,758	517,235	484,145
Operating expenses				
Cost of product sales, license fees and royalties [(1)]	2,413	2,561	10,166	19,141
Research and development [(1)]	75,738	67,084	361,575	239,415
Selling, general and administrative [(1)]	104,402	105,770	369,090	396,028
Total operating expenses	182,553	175,415	740,831	654,584
Loss from operations	(46,063)	(44,657)	(223,596)	(170,439)
Interest income, net	3,630	129	6,610	591
Other income	1,543	1,623	3,542	2,329
Loss before income taxes	(40,890)	(42,905)	(213,444)	(167,519)
Income tax expense	835	189	2,531	351
Net loss	$ (41,725)	$ (43,094)	$ (215,975)	$ (167,870)
Net loss per common share, basic and diluted	$ (0.26)	$ (0.27)	$ (1.34)	$ (1.05)
Weighted average common shares outstanding, basic and diluted	161,988	160,866	161,683	160,493

[(1)] Includes the following share-based compensation expenses

Cost of product sales, license fees and royalties	$ 93	$ 261	$ 1,106	$ 1,286
Research and development	$ 3,432	$ 4,644	$ 22,580	$ 21,969
Selling, general and administrative	$ 10,889	$ 7,975	$ 44,515	$ 40,360

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

	December 31, 2022	December 31, 2021
	(unaudited)	
Assets		
Cash, cash equivalents and investment securities	$ 416,823	$ 520,706
Accounts receivable, net	62,195	64,366
Interest and other receivables	885	978
Inventory	6,636	7,881
Prepaid expenses	21,398	23,892
Total current assets	507,937	617,823
Property and equipment, net	6,021	8,047
Operating lease right-of-use assets	55,573	58,268
Restricted cash	5,770	5,770
Long-term inventory	4,924	6,217
Other assets	7,587	3,997
Total assets	$ 587,812	$ 700,122
Liabilities and stockholders' equity		
Accounts payable	$ 12,746	$ 6,876
Accrued liabilities	112,884	89,192
Total current liabilities	125,630	96,068
Operating lease liabilities	52,695	56,126
Long-term liabilities	9,074	7,034
Total liabilities	187,399	159,228
Total stockholders' equity	400,413	540,894
Total liabilities and stockholders' equity	$ 587,812	$ 700,122

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

Investor Contact:
Acadia Pharmaceuticals Inc.
Mark Johnson, CFA
(858) 261-2771
ir@acadia-pharm.com