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 08, 2022

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 August 8, 2022, Acadia Pharmaceuticals Inc. issued a press release announcing its financial results for the second quarter and six months ended June 30, 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 August 8, 2022.
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 8, 2022

By: /s/ Austin D. Kim
Austin D. Kim
Executive Vice President, General Counsel & Secretary

Exhibit 99.1

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Acadia Pharmaceuticals Reports
Second Quarter 2022 Financial Results

- 2Q22 net sales of $134.6 million, a 17% increase over 2Q21

- NDA submitted for trofinetide for the treatment of Rett syndrome

SAN DIEGO, CA, August 8, 2022 – Acadia Pharmaceuticals Inc. (Nasdaq: ACAD), today announced its financial results for the second quarter ended June 30, 2022.

"In the second quarter of 2022, NUPLAZID net sales increased 17% year-over-year," said Steve Davis, Chief Executive Officer. "Last month, we submitted an NDA for our second potential commercial product, trofinetide which would be the first FDA-approved treatment for Rett syndrome. Together with a strong balance sheet, our late and early-stage portfolio, including our Phase 3 program for pimavanserin for the treatment of the negative symptoms of schizophrenia, and a continued focus on strategic business development, we are well-positioned for long-term growth."

Company Updates

- Submitted a New Drug Application (NDA) to the FDA for trofinetide as a potential treatment for Rett syndrome in adults and pediatric patients two years of age and older. Trofinetide could be Acadia's second commercial product and the first and only approved treatment in the U.S. for Rett syndrome.

- Received a Complete Response Letter from the FDA for the resubmitted supplemental NDA for pimavanserin for the treatment of hallucinations and delusions associated with Alzheimer's disease psychosis (ADP).

- Presented two late-breaker posters at the American Society of Clinical Psychopharmacology (ASCP) Annual Meeting in June 2022, adding to the growing body of evidence of safety of pimavanserin in the treatment of Parkinson's disease psychosis.

- Acadia is developing an internally discovered new molecule, ACP-204, currently in Phase 1. ACP-204 builds upon the learnings of pimavanserin in the treatment of neuropsychiatric symptoms.

- Acadia is discontinuing the development of ACP-044 in acute and chronic pain, based on evaluation of the final data set from a previously completed Phase 2 bunionectomy study, and ACP-319 an M1 PAM modulator, based on a profile that does not support advancement to Phase 2.

Financial Results

Revenue
Net sales of NUPLAZID® (pimavanserin) were $134.6 million for the three months ended June 30, 2022, an increase of 17% as compared to $115.2 million reported for the three months ended June 30, 2021. For the six months ended June 30, 2022 and 2021, Acadia reported net product sales of $250.0 million and $221.8 million, respectively.

Research and Development
Research and development expenses for the three months ended June 30, 2022 were $75.6 million, compared to $56.9 million for the same period of 2021. The increase was primarily due to increased costs of our development activities for ACP-044, ACP-319 and other early stage programs. For the six months ended June 30, 2022 and 2021, research and development expenses were $204.5 million and $113.9 million. The increase was mainly due to the $60 million upfront payment made to Stoke Therapeutics for the license and collaboration agreement in 2022.

Selling, General and Administrative
Selling, general and administrative expenses for the three months ended June 30, 2022 were $89.9 million, compared to $96.8 million for the same period of 2021. For the six months ended June 30, 2022 and 2021, selling, general and administrative expenses were $186.6 million and $208.5 million, respectively. The decrease in both periods was primarily due to decreased advertising and promotional costs and personnel expenses.

Net Loss
For the three months ended June 30, 2022, Acadia reported a net loss of $34.0 million, or $0.21 per common share, compared to a net loss of $43.9 million, or $0.27 per common share, for the same period in 2021. The net losses for the three months ended June 30, 2022 and 2021 included $20.5 million and $22.0 million, respectively, of non-cash stock-based compensation expense. For the six months ended June 30, 2022, Acadia reported a net loss of $147.1 million, or $0.91 per common share, compared to a net loss of $110.3 million, or $0.69 per common share, for the same period in 2021. The increase was mainly due to the $60 million upfront payment made to Stoke Therapeutics for the license and collaboration agreement in 2022. The net losses for the six months ended June 30, 2022 and 2021 included $35.5 million and $35.2 million, respectively, of non-cash stock-based compensation expense.

Cash and Investments
At June 30, 2022, Acadia's cash, cash equivalents, and investment securities totaled $436.4 million, compared to $520.7 million at December 31, 2021.

2022 Financial Guidance

- NUPLAZID net sales guidance is updated to $510 to $540 million from the previous range of $510 to $560 million.
- GAAP R&D guidance is updated to $340 to $360 million from $355 to $375 million, which includes approximately $25 million of stock-based compensation expense.
- GAAP SG&A guidance of $360 to $380 million is reiterated, 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 September 5, 2022.

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 in other neuropsychiatric conditions.

About Trofinetide
Trofinetide is an investigational drug. It is a novel synthetic analog of the amino-terminal tripeptide of IGF-1 designed to treat the core symptoms of Rett syndrome by potentially reducing neuroinflammation and supporting synaptic function. Trofinetide is thought to stimulate synaptic maturation and overcome the synaptic and neuronal immaturities that are characteristic of Rett syndrome pathophysiology. In the central nervous system, IGF-1 is produced by both of the major types of brain cells – neurons and glia. IGF-1 in the brain is critical for both normal development and for response to injury and disease. Trofinetide has been shown to inhibit the production of inflammatory cytokines, inhibit the overactivation of microglia and astrocytes, and increase the amount of available IGF-1 that can bind to IGF-1 receptors. Trofinetide has been granted Fast Track Status and Orphan Drug Designation for Rett syndrome and has also been granted Rare Pediatric Disease (RPD) designation by the FDA.

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 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 related to: the potential opportunity for future growth in sales of NUPLAZID; the timing of ongoing and future clinical studies for pimavanserin; the development and commercialization of trofinetide; and guidance for full-year 2022 NUPLAZID net sales for Parkinson's disease psychosis only and certain expense line items. 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 uncertainty of future commercial sales and related items that would impact net sales during 2022, the risks and uncertainties inherent in drug development, approval and commercialization, and the fact that past results of clinical trials may not be indicative of future trial results. 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.

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,	
	2022	2021	2022	2021
Revenues				
Product sales, net	$ 134,563	$ 115,221	$ 250,031	$ 221,775
Total revenues	134,563	115,221	250,031	221,775
Operating expenses				
Cost of product sales, license fees and royalties [1]	2,667	5,206	5,617	9,898
Research and development [1]	75,646	56,935	204,501	113,908
Selling, general and administrative [1]	89,901	96,789	186,580	208,450
Total operating expenses	168,214	158,930	396,698	332,256
Loss from operations	(33,651)	(43,709)	(146,667)	(110,481)
Interest income, net	580	133	685	333
Other (loss) income	(497)	178	(157)	323
Loss before income taxes	(33,568)	(43,398)	(146,139)	(109,825)
Income tax expense	443	473	928	494
Net loss	$ (34,011)	$ (43,871)	$ (147,067)	$ (110,319)
Net loss per common share, basic and diluted	$ (0.21)	$ (0.27)	$ (0.91)	$ (0.69)
Weighted average common shares outstanding, basic and diluted	161,654	160,421	161,443	160,217

[1] Includes the following stock-based compensation expense

Cost of product sales, license fees and royalties	$ 346	$ 423	$ 669	$ 586
Research and development	$ 7,232	$ 7,319	$ 12,696	$ 12,149
Selling, general and administrative	$ 12,934	$ 14,263	$ 22,110	$ 22,454

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

	June 30, 2022	December 31, 2021
	(unaudited)	
Assets		
Cash, cash equivalents and investment securities	$ 436,351	$ 520,706
Accounts receivable, net	67,953	64,366
Interest and other receivables	936	978
Inventory	6,327	7,881
Prepaid expenses	20,952	23,892
Total current assets	532,519	617,823
Property and equipment, net	7,016	8,047
Operating lease right-of-use assets	57,417	58,268
Restricted cash	5,770	5,770
Long-term inventory	6,205	6,217
Other assets	3,839	3,997
Total assets	$ 612,766	$ 700,122
Liabilities and stockholders' equity		
Accounts payable	$ 11,854	$ 6,876
Accrued liabilities	105,827	89,192
Total current liabilities	117,681	96,068
Operating lease liabilities	54,693	56,126
Other long-term liabilities	5,544	7,034
Total liabilities	177,918	159,228
Total stockholders' equity	434,848	540,894
Total liabilities and stockholders' equity	$ 612,766	$ 700,122

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