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 4, 2021

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 is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. of Form 8-K):

☐ 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 4, 2021, Acadia Pharmaceuticals Inc. issued a press release announcing its financial results for the second quarter and six months ended June 30, 2021. 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 4, 2021.
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 hereunto duly authorized.

ACADIA Pharmaceuticals Inc.

Dated: August 4, 2021

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

Exhibit 99.1

Acadia Pharmaceuticals Reports
Second Quarter 2021 Financial Results

- 2Q21 net sales of $115.2 million, a 5% increase over 2Q20

- Fiscal year 2021 revenue guidance reduced to $480 to $515 million

- Type A meeting held with FDA regarding DRP; Acadia will continue discussion with FDA in another meeting later this year

SAN DIEGO, CA, August 4, 2021 – Acadia Pharmaceuticals Inc. (Nasdaq: ACAD), today announced its financial results for the second quarter ended June 30, 2021.

“NUPLAZID performed well in the second quarter of 2021, highlighted by our ability to drive growth while still navigating the continued impact from the pandemic,” said Steve Davis, Chief Executive Officer. “We recently completed a Type A meeting with the FDA regarding pimavanserin for dementia-related psychosis and plan to continue our engagement in another meeting with the FDA later this year to further discuss potential paths to approval. Looking ahead, we plan to announce top-line results by the end of the year from our Phase 3 study in Rett syndrome and our proof-of-concept Phase 2 study in postoperative pain.”

Company Updates

- Completed a Type A End of Review meeting regarding the FDA’s complete response letter (CRL) for the sNDA for pimavanserin for the treatment of hallucinations and delusions associated with dementia-related psychosis (DRP). At the meeting, the FDA reiterated their stated position in the CRL, that pimavanserin should be studied by individual subgroups of dementia, and advised that the best path forward is to conduct an additional clinical study in each of the subgroups for which we seek approval. However, the FDA also indicated that they are open to having another meeting to discuss additional analyses from the HARMONY and -019 studies in support of a potential resubmission without an additional clinical study.

- The *New England Journal of Medicine* published the positive results from the Phase 3 HARMONY study evaluating pimavanserin in patients with dementia-related psychosis in July 2021.

- Results from an open-label extension safety study with pimavanserin supporting sustained response in Parkinson’s disease psychosis patients was published online in the June 2021 issue of *Parkinsonism and Related Disorders.*

- Completed enrollment of the Phase 3 LAVENDER study evaluating trofinetide for the treatment of Rett syndrome, with top-line results expected in the fourth quarter of 2021.

- Initiated a Phase 2 study of ACP-044 for pain associated with osteoarthritis in the second quarter of 2021.

- Top-line results from the Phase 2 study of ACP-044 for the treatment of postoperative pain following bunionectomy surgery are expected in the fourth quarter of 2021.

Financial Results

Revenue
Net sales of NUPLAZID® (pimavanserin) were $115.2 million for the three months ended June 30, 2021, an increase of 5% as compared to $110.1 million reported for the three months ended June 30, 2020. For the six months ended June 30, 2021 and 2020, Acadia reported net product sales of $221.8 million and $200.2 million, respectively.

Research and Development
Research and development expenses for the three months ended June 30, 2021 were $56.9 million, compared to $64.3 million for the same period of 2020. The decrease in the three month period ending June 2021 compared to June 2020 was largely due to the cessation of development costs of pimavanserin for major depressive disorder and lower development costs for DRP. For the six months ended June 30, 2021 and 2020, research and development expenses were $113.9 million and $136.9 million. The decrease for the six month period ending June 2021 compared to June 2020 was largely due to lower development costs of pimavanserin and trofinetide, partially offset by increased development costs for ACP-044.

Selling, General and Administrative
Selling, general and administrative expenses for the three months ended June 30, 2021 were $96.8 million, compared to $84.3 million for the same period of 2020. The increase for the three month period ending June 2021 compared to June 2020 was primarily due to increased costs associated with advertising and promotion, corporate support functions and stock-based compensation. For the six months ended June 30, 2021 and 2020, selling, general and administrative expenses were $208.5 million and $186.3 million, respectively. The increase for the six month period ending June 2021 compared to June 2020 was primarily due to increased costs associated with advertising, promotion and preparations for the potential DRP launch.

Net Loss
For the three months ended June 30, 2021, Acadia reported a net loss of $43.9 million, or $0.27 per common share, compared to a net loss of $42.1 million, or $0.27 per common share, for the same period in 2020. The net losses for the three months ended June 30, 2021 and 2020 included $22.0 million and $19.5 million, respectively, of non-cash stock-based compensation expense. For the six months ended June 30, 2021, Acadia reported a net loss of $110.3 million, or $0.69 per common share, compared to a net loss of $130.2 million, or $0.83 per common share, for the same period in 2020. The net losses for the six months ended June 30, 2021 and 2020 included $35.2 million and $41.9 million, respectively, of non-cash stock-based compensation expense.

Cash and Investments
At June 30, 2021, Acadia's cash, cash equivalents, and investment securities totaled $556.9 million, compared to $632.0 million at December 31, 2020.

2021 Financial Guidance

- NUPLAZID net sales guidance is decreased to $480 to $515 million from the previous range of $510 to $550 million as a result of the continued impact of the pandemic with fewer Parkinson's disease patient office visits and lower occupancy rates at long-term care facilities, as well as a revised gross-to-net expectation of approximately 20% compared to prior expectation of high teens.

- GAAP R&D is decreased to $250 to $270 million from the previous range of $280 to $300 million. Current R&D guidance includes approximately $25 million of stock-based compensation expense.

- GAAP SG&A guidance is reiterated at $385 to $415 million. Current SG&A guidance includes approximately $50 million of stock-based compensation expense.

Conference Call and Webcast Information
Acadia management will review its second quarter financial results and operations via conference call and webcast today at 4:30 p.m. Eastern Time. The conference call may be accessed by dialing 855-638-4820 for participants in the United States or Canada and 443-877-4067 for international callers (reference passcode 8065926). A telephone replay of the conference call may be accessed through August 18, 2021 by dialing 855-859-2056 for callers in the United States or Canada and 404-537-3406 for international callers (reference passcode 8065926). The conference call also will be webcast live on Acadia's website, www.acadia-pharm.com under the investors section and will be archived there until September 1, 2021.

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. NUPLAZID is not approved for dementia-related psychosis. 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. 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 granted Fast Track Status and Orphan Drug Designation in the U.S. and Orphan Drug Designation in Europe for both Rett syndrome and Fragile X syndrome.

About Acadia Pharmaceuticals
Acadia is trailblazing 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 late-stage development efforts are focused on dementia-related psychosis, negative symptoms of schizophrenia and Rett syndrome, and in early-stage clinical research we are exploring novel approaches to pain management, and cognition and neuropsychiatric symptoms in central nervous system disorders. For more information, visit us at www.acadia-pharm.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 2021 NUPLAZID net sales for Parkinson's disease psychosis 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 2021, 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, 2020 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,	
	2021	2020	2021	2020
Revenues				
Product sales, net	$ 115,221	$ 110,103	$ 221,775	$ 200,171
Total revenues	115,221	110,103	221,775	200,171
Operating expenses				
Cost of product sales, license fees and royalties (1)	5,206	5,474	9,898	10,448
Research and development (1)	56,935	64,295	113,908	136,931
Selling, general and administrative (1)	96,789	84,344	208,450	186,317
Total operating expenses	158,930	154,113	332,256	333,696
Loss from operations	(43,709)	(44,010)	(110,481)	(133,525)
Interest income, net	133	1,825	333	4,814
Other income (expense)	178	437	323	(1,060)
Loss before income taxes	(43,398)	(41,748)	(109,825)	(129,771)
Income tax expense	473	393	494	393
Net loss	$ (43,871)	$ (42,141)	$ (110,319)	$ (130,164)
Net loss per common share, basic and diluted	$ (0.27)	$ (0.27)	$ (0.69)	$ (0.83)
Weighted average common shares outstanding, basic and diluted	160,421	156,535	160,217	155,951

(1) Includes the following stock-based compensation expense

Cost of product sales, license fees and royalties	$ 423	$ 743	$ 586	$ 1,592
Research and development	$ 7,319	$ 7,235	$ 12,149	$ 15,692
Selling, general and administrative	$ 14,263	$ 11,529	$ 22,454	$ 24,571

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

	June 30, 2021 (unaudited)	December 31, 2020
Assets		
Cash, cash equivalents and investment securities	$ 556,918	$ 631,958
Accounts receivable, net	51,367	48,247
Interest and other receivables	453	2,035
Inventory	10,786	9,682
Prepaid expenses	26,206	25,694
Total current assets	645,730	717,616
Property and equipment, net	9,197	9,161
Operating lease right-of-use assets	61,371	47,283
Intangible assets, net	369	1,108
Restricted cash	5,770	5,770
Other assets	1,992	1,678
Total assets	$ 724,429	$ 782,616
Liabilities and stockholders' equity		
Accounts payable	$ 9,065	$ 8,493
Accrued liabilities	86,263	97,474
Total current liabilities	95,328	105,967
Operating lease liabilities	59,134	44,460
Other long-term liabilities	5,129	5,180
Total liabilities	159,591	155,607
Total stockholders' equity	564,838	627,009
Total liabilities and stockholders' equity	$ 724,429	$ 782,616

Media Contact:
Acadia Pharmaceuticals Inc.
Eric Endicott
(858) 914-7161
media@acadia-pharm.com

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