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): May 5, 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 May 5, 2021, Acadia Pharmaceuticals Inc. issued a press release announcing its financial results for the three months ended March 31, 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 May 5, 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: May 5, 2021

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

Exhibit 99.1

Acadia Pharmaceuticals Reports
First Quarter 2021 Financial Results

- 1Q21 net sales of $106.6 million, an 18% increase over 1Q20

- Reiterating FY21 net sales guidance of $510 to $550 million

SAN DIEGO, CA, May 5, 2021 – Acadia Pharmaceuticals Inc. (Nasdaq: ACAD), today announced its financial results for the first quarter ended March 31, 2021.

“NUPLAZID delivered strong year-over-year performance in the first quarter of 2021. Looking ahead, we see positive signs in the Parkinson’s disease psychosis market supporting revenue growth for the remainder of the year as we anticipate continued improvements in the conditions related to the pandemic,” said Steve Davis, Chief Executive Officer. “Furthermore, we look forward to a Type A meeting with the FDA to discuss an approval path for pimavanserin in dementia-related psychosis and we continue to advance our two Phase 3 programs for Rett syndrome and the negative symptoms of schizophrenia, as well as our Phase 2 pain program and earlier pipeline opportunities.”

Company Updates

- The Company received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding its supplemental New Drug Application (sNDA) for NUPLAZID® (pimavanserin) for the treatment of hallucinations and delusions associated with dementia-related psychosis (DRP). The Company plans to conduct a Type A meeting with the FDA to discuss the CRL and potential next steps to support an approval.

- Top-line results from the Phase 3 LAVENDER study evaluating trofinetide for the treatment of Rett syndrome are expected in the fourth quarter of 2021.

- A Phase 2 study was initiated evaluating ACP-044, a novel, first-in-class, orally administered, non-opioid analgesic for the treatment of postoperative pain following bunionectomy surgery in March 2021.

- A Phase 2 study evaluating ACP-044 for the treatment of pain associated with osteoarthritis is expected to commence in the second quarter of 2021.

Financial Results

Revenue
Net sales of NUPLAZID (pimavanserin) were $106.6 million for the three months ended March 31, 2021, an increase of 18% as compared to $90.1 million reported for the three months ended March 31, 2020.

Research and Development
Research and development expenses for the three months ended March 31, 2021 were $57.0 million, compared to $72.6 million for the same period of 2020. This decrease was primarily due to the $10.0 million upfront payment to Vanderbilt University for the M1 PAM program incurred during the three months ended March 31, 2020 and decreased development costs associated with pimavanserin for major depressive disorder.

Selling, General and Administrative
Selling, general and administrative expenses for the three months ended March 31, 2021 were $111.7 million, compared to $102.0 million for the same period of 2020. This increase was primarily due to increased costs associated with preparations for the potential DRP launch, partially offset by a decrease in stock-based compensation expense.

Net Loss
For the three months ended March 31, 2021, Acadia reported a net loss of $66.4 million, or $0.42 per common share, compared to a net loss of $88.0 million, or $0.57 per common share, for the same period in 2020. The net losses for the three months ended March 31, 2021 and 2020 included $13.2 million and $22.3 million, respectively, of non-cash stock-based compensation expense.

Cash and Investments
At March 31, 2021, Acadia's cash, cash equivalents, and investment securities totaled $577.8 million, compared to $632.0 million at December 31, 2020.

2021 Financial Guidance

- Acadia is reiterating its NUPLAZID net sales guidance of $510 to $550 million.
- GAAP R&D guidance is decreased to $280 to $300 million from the previous range of $300 to $320 million. Current R&D guidance includes approximately $25 million of stock-based compensation expense.
- GAAP SG&A guidance is decreased to $385 to $415 million from the previous range of $560 to $590 million. Previous guidance included additional investments associated with the potential DRP launch in 2021 and updated guidance reflects a reduction in these expenses. Current SG&A guidance includes approximately $50 million of stock-based compensation expense.

Conference Call and Webcast Information
Acadia management will review its first quarter financial results and operations via conference call and webcast today at 5:00 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 4568937). A telephone replay of the conference call may be accessed through May 19, 2021 by dialing 855-859-2056 for callers in the United States or Canada and 404-537-3406 for international callers (reference passcode 4568937). The conference call also will be webcast live on Acadia's website, w w w . a c a d i a - p h a r m . c o m , under the investors section and will be archived there until June 2, 2021.

About NUPLAZID® (pimavanserin)
NUPLAZID is the first and only FDA-approved treatment for hallucinations and delusions associated with Parkinson's disease psychosis. NUPLAZID is a selective serotonin inverse agonist/antagonist preferentially targeting 5-HT2A receptors that are thought to play an important role in Parkinson's disease psychosis. NUPLAZID is an oral medicine taken once a day with a recommended dose of 34 mg. NUPLAZID is not approved for any other neuropsychiatric disorders. Acadia discovered and developed this new chemical entity and holds worldwide rights to develop and commercialize NUPLAZID.

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 w w w . a c a d i a - p h a r m . c o m and follow us on LinkedIn.

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 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 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 March 31,	
	2021	2020
Revenues		
Product sales, net	$ 106,554	$ 90,068
Total revenues	106,554	90,068
Operating expenses		
Cost of product sales, license fees and royalties (1)	4,692	4,974
Research and development (1)	56,973	72,636
Selling, general and administrative (1)	111,661	101,973
Total operating expenses	173,326	179,583
Loss from operations	(66,772)	(89,515)
Interest income, net	200	2,989
Other income (expense)	145	(1,497)
Loss before income taxes	(66,427)	(88,023)
Income tax expense	21	—
Net loss	$ (66,448)	$ (88,023)
Net loss per common share, basic and diluted	$ (0.42)	$ (0.57)
Weighted average common shares outstanding, basic and diluted	160,011	155,368

(1) Includes the following stock-based compensation expense

Cost of product sales, license fees and royalties	$ 163	$ 849
Research and development	$ 4,830	$ 8,457
Selling, general and administrative	$ 8,191	$ 13,042

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

	March 31, 2021 (unaudited)	December 31, 2020
Assets		
Cash, cash equivalents and investment securities	$ 577,768	$ 631,958
Accounts receivable, net	56,832	48,247
Interest and other receivables	558	2,035
Inventory	10,311	9,682
Prepaid expenses	28,515	25,694
Total current assets	673,984	717,616
Property and equipment, net	9,757	9,161
Operating lease right-of-use assets	63,111	47,283
Intangible assets, net	738	1,108
Restricted cash	5,770	5,770
Other assets	1,813	1,678
Total assets	$ 755,173	$ 782,616
Liabilities and stockholders' equity		
Accounts payable	$ 8,849	$ 8,493
Accrued liabilities	100,524	97,474
Total current liabilities	109,373	105,967
Operating lease liabilities	60,581	44,460
Other long-term liabilities	3,613	5,180
Total liabilities	173,567	155,607
Total stockholders' equity	581,606	627,009
Total liabilities and stockholders' equity	$ 755,173	$ 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