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 8, 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 November 8, 2021, Acadia Pharmaceuticals Inc. issued a press release announcing its financial results for the third quarter and nine months ended September 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 November 8, 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: November 8, 2021

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

Exhibit 99.1

Acadia Pharmaceuticals Reports
Third Quarter 2021 Financial Results

- 3Q21 net sales of $131.6 million, a 9% increase over 3Q20

- FDA meeting scheduled to discuss next steps towards a resubmission of the pimavanserin sNDA

SAN DIEGO, CA, November 8, 2021 – Acadia Pharmaceuticals Inc. (Nasdaq: ACAD), today announced its financial results for the third quarter ended September 30, 2021.

“Our third-quarter results reflect volume growth across all channels and our strong relative performance underscores our commercial team’s ability to drive sales of NUPLAZID in a challenging environment,” said Steve Davis, Chief Executive Officer. “As we close out the year, we will meet with the FDA to discuss additional analyses supporting a potential resubmission of our sNDA for pimavanserin focused on specific subgroups of dementia. In addition, we look forward to announcing results from our ongoing Phase 3 LAVENDER study of trofinetide for the treatment of Rett syndrome.”

Company Updates

- Scheduled meeting with the FDA to discuss additional analyses supporting a potential resubmission of the pimavanserin sNDA focused on specific subgroups of dementia. Acadia plans to provide an update following this meeting around year-end.
- 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.
- Top-line results from the Phase 2 study of ACP-044 for the treatment of postoperative pain following bunionectomy surgery are expected in the first quarter of 2022.
- Three data presentations featuring new analyses of Medicare claims data on dementia-related psychosis outcomes were presented at the Psych Congress 2021 demonstrating the high unmet need in dementia-related psychosis and providing further evidence of the sub-optimal outcomes associated with the use of dopaminergic atypical antipsychotic treatments in managing dementia-related hallucinations and delusions, along with the related cost burdens.
- A scientific presentation on pimavanserin for the treatment of hallucinations and delusions in patients with Parkinson’s disease dementia will be shared at the 14th Clinical Trials on Alzheimer’s Disease (CTAD) conference.
- Brendan Teehan has been promoted to Executive Vice President, Chief Operating Officer, Head of Commercial.

- Julie Fisher has been promoted to Senior Vice President, Marketing & Commercial Strategy. Ms. Fisher will report to Mr. Teehan and join the company's Executive Management Committee.

Financial Results

Revenue
Net sales of NUPLAZID® (pimavanserin) were $131.6 million for the three months ended September 30, 2021, an increase of 9% as compared to $120.6 million reported for the three months ended September 30, 2020. For the nine months ended September 30, 2021 and 2020, Acadia reported net product sales of $353.4 million and $320.7 million, respectively.

Research and Development
Research and development expenses for the three months ended September 30, 2021 were $58.6 million, compared to $120.1 million for the same period of 2020. The decrease was largely due to decreased costs associated with the upfront consideration and transaction costs related to the acquisition of CerSci Therapeutics. For the nine months ended September 30, 2021 and 2020, research and development expenses were $172.5 million and $257.0 million. The decrease was largely due to the acquisition of CerSci Therapeutics and reduced development costs for trofinetide and the cessation of development of pimavanserin for major depressive disorder, partially offset by increased costs of our development activities for ACP-044.

Selling, General and Administrative
Selling, general and administrative expenses for the three months ended September 30, 2021 were $81.7 million, compared to $81.6 million for the same period of 2020. For the nine months ended September 30, 2021 and 2020, selling, general and administrative expenses were $290.1 million and $267.9 million, respectively. The increase was primarily due to increased advertising and promotional costs as well as an increase in personnel and related costs.

Net Loss
For the three months ended September 30, 2021, Acadia reported a net loss of $14.5 million, or $0.09 per common share, compared to a net loss of $84.7 million, or $0.54 per common share, for the same period in 2020. The net losses for the three months ended September 30, 2021 and 2020 included $15.5 million and $21.4 million, respectively, of non-cash stock-based compensation expense. For the nine months ended September 30, 2021, Acadia reported a net loss of $124.8 million, or $0.78 per common share, compared to a net loss of $214.8 million, or $1.37 per common share, for the same period in 2020. The net losses for the nine months ended September 30, 2021 and 2020 included $50.7 million and $63.2 million, respectively, of non-cash stock-based compensation expense.

Cash and Investments
At September 30, 2021, Acadia's cash, cash equivalents, and investment securities totaled $540.3 million, compared to $632.0 million at December 31, 2020.

2021 Financial Guidance

- NUPLAZID net sales guidance is narrowed to $480 to $500 million from the previous range of $480 to $515 million.
- GAAP R&D is decreased to $230 to $245 million from the previous range of $250 to $270 million. Current R&D guidance includes approximately $25 million of stock-based compensation expense.
- GAAP SG&A guidance is narrowed to $385 to $405 million from the previous range of $385 to $415 million. Current SG&A guidance includes approximately $45 million of stock-based compensation expense.

Conference Call and Webcast Information
Acadia management will review its third 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 9213599). A telephone replay of the conference call may be accessed through November 22, 2021 by dialing 855-859-2056 for callers in the United States or Canada and 404-537-3406 for international callers (reference passcode 9213599). 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 December 6, 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenues				
Product sales, net	$ 131,612	$ 120,577	$ 353,387	$ 320,748
Total revenues	131,612	120,577	353,387	320,748
Operating expenses				
Cost of product sales, license fees and royalties (1)	6,682	4,801	16,580	15,249
Research and development (1)	58,565	120,083	172,473	257,014
Selling, general and administrative (1)	81,666	81,592	290,116	267,909
Total operating expenses	146,913	206,476	479,169	540,172
Loss from operations	(15,301)	(85,899)	(125,782)	(219,424)
Interest income, net	129	1,242	462	6,056
Other income (expense)	383	(202)	706	(1,262)
Loss before income taxes	(14,789)	(84,859)	(124,614)	(214,630)
Income tax expense	(332)	(199)	162	194
Net loss	$ (14,457)	$ (84,660)	$ (124,776)	$ (214,824)
Net loss per common share, basic and diluted	$ (0.09)	$ (0.54)	$ (0.78)	$ (1.37)
Weighted average common shares outstanding, basic and diluted	160,663	158,129	159,651	156,683

(1) Includes the following stock-based compensation expense

Cost of product sales, license fees and royalties	$ 439	$ 495	$ 1,025	$ 2,087
Research and development	$ 5,176	$ 7,953	$ 17,325	$ 23,645
Selling, general and administrative	$ 9,931	$ 12,924	$ 32,385	$ 37,495

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

	September 30, 2021 (unaudited)	December 31, 2020
Assets		
Cash, cash equivalents and investment securities	$ 540,291	$ 631,958
Accounts receivable, net	60,696	48,247
Interest and other receivables	972	2,035
Inventory	14,336	9,682
Prepaid expenses	24,622	25,694
Total current assets	640,917	717,616
Property and equipment, net	8,581	9,161
Operating lease right-of-use assets	60,032	47,283
Restricted cash	5,770	5,770
Other assets	2,373	2,786
Total assets	$ 717,673	$ 782,616
Liabilities and stockholders' equity		
Accounts payable	$ 7,722	$ 8,493
Accrued liabilities	80,496	97,474
Total current liabilities	88,218	105,967
Operating lease liabilities	57,677	44,460
Other long-term liabilities	4,823	5,180
Total liabilities	150,718	155,607
Total stockholders' equity	566,955	627,009
Total liabilities and stockholders' equity	$ 717,673	$ 782,616

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