# 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 04, 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** | **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 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 May 4, 2022, Acadia Pharmaceuticals Inc. issued a press release announcing its financial results for the three months ended March 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 May 4, 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: May 4, 2022

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

**Acadia Pharmaceuticals Reports**
**First Quarter 2022 Financial Results**

*- 1Q22 net sales of $115.5 million, an 8% increase over 1Q21*

*- Reiterating FY22 net sales guidance of $510 to $560 million*

*- FDA Advisory Committee meeting to review sNDA for pimavanserin for the treatment of ADP scheduled for June 17, 2022*

**SAN DIEGO, CA, May 4, 2022** – Acadia Pharmaceuticals Inc. (Nasdaq: ACAD), today announced its financial results for the first quarter ended March 31, 2022.

“NUPLAZID continued to deliver year over year growth in the first quarter of 2022,” said Steve Davis, Chief Executive Officer. “In the near term, we are focused on preparing for the upcoming Advisory Committee meeting in connection with our resubmitted sNDA for pimavanserin in Alzheimer’s disease psychosis. In addition, we have aligned with the FDA on the contents of our upcoming NDA submission for trofinetide in Rett syndrome and continue to enroll patients in our ongoing Phase 3 study evaluating pimavanserin for the negative symptoms of schizophrenia.”

**Company Highlights**

- The U.S. Food and Drug Administration (FDA) Advisory Committee meeting is scheduled for June 17, 2022 to review the resubmission of the supplemental New Drug Application (sNDA) for pimavanserin for the treatment of hallucinations and delusions associated with Alzheimer’s disease psychosis (ADP).

- The FDA is targeting an August 4, 2022 action date for the resubmitted sNDA for pimavanserin for the treatment of ADP.

- Trofinetide for the treatment of Rett syndrome remains on track for an NDA submission around mid-year 2022.

- Late-breaker oral presentation on the efficacy and safety data from the Phase 3 Lavender study of trofinetide was presented at the 2022 American Academy of Neurology Annual Meeting (AAN) on April 5, 2022.

- Parag Meswani joined Acadia as Senior Vice President, Trofinetide - Rare Disease Franchise to lead the trofinetide commercial effort. In addition, Holly Valdiviez joined Acadia as Senior Vice President, Head of Sales for NUPLAZID. Parag and Holly have joined Acadia’s Executive Management Committee.

**Financial Results**

*Revenue*
Net sales of NUPLAZID (pimavanserin) were $115.5 million for the three months ended March 31, 2022, an increase of 8% as compared to $106.6 million reported for the three months ended March 31, 2021.

*Research and Development*
Research and development expenses for the three months ended March 31, 2022 were $128.9 million, compared to $57.0 million for the same period of 2021. This increase was primarily due to expensing of the $60.0 million upfront payment made to Stoke Therapeutics under the license and collaboration agreement made in January 2022.

*Selling, General and Administrative*
Selling, general and administrative expenses for the three months ended March 31, 2022 were $96.7 million, compared to $111.7 million for the same period of 2021. This decrease was primarily due to decreased advertising and promotional costs and decreased personnel expenses.

*Net Loss*
For the three months ended March 31, 2022, Acadia reported a net loss of $113.1 million, or $0.70 per common share, compared to a net loss of $66.4 million, or $0.42 per common share, for the same period in 2021. This increase in net loss was primarily due to expensing of the $60.0 million upfront payment made to Stoke Therapeutics under the license and collaboration agreement made in January 2022. The net losses for the three months ended March 31, 2022 and 2021 included $15.0 million and $13.2 million, respectively, of non-cash stock-based compensation expense.

*Cash and Investments*
At March 31, 2022, Acadia's cash, cash equivalents, and investment securities totaled $446.0 million, compared to $520.7 million at December 31, 2021.

**2022 Financial Guidance**

Acadia is reiterating its previously provided guidance ranges:

- NUPLAZID net sales guidance of $510 to $560 million.
- GAAP R&D guidance of $355 to $375 million, which includes approximately $25 million of stock-based compensation expense.
- GAAP SG&A guidance of $360 to $380 million, which includes approximately $45 million of stock-based compensation expense.

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*Conference Call and Webcast Information*
Acadia management will review its first 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 6989476). A telephone replay of the conference call may be accessed through May 19, 2022 by dialing 855-859-2056 for callers in the United States or Canada and 404-537-3406 for international callers (reference passcode 6989476). 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 June 1, 2022.

*About NUPLAZID® (pimavanserin)*
Pimavanserin is a selective serotonin inverse agonist and antagonist preferentially targeting 5-$HT_{2A}$ 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 Alzheimer's disease 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. 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 late-stage development efforts are focused on treating psychosis in patients with dementia, the negative symptoms of schizophrenia and Rett syndrome. Our early-stage development efforts are focused on novel approaches to pain management, 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 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 March 31, | |
|---|---|---|
| | 2022 | 2021 |
| **Revenues** | | |
| Product sales, net | $ 115,468 | $ 106,554 |
| Total revenues | 115,468 | 106,554 |
| **Operating expenses** | | |
| Cost of product sales, license fees and royalties [1] | 2,950 | 4,692 |
| Research and development [1] | 128,855 | 56,973 |
| Selling, general and administrative [1] | 96,679 | 111,661 |
| Total operating expenses | 228,484 | 173,326 |
| Loss from operations | (113,016) | (66,772) |
| Interest income, net | 105 | 200 |
| Other income | 340 | 145 |
| Loss before income taxes | (112,571) | (66,427) |
| Income tax expense | 485 | 21 |
| Net loss | $ (113,056) | $ (66,448) |
| Net loss per common share, basic and diluted | $ (0.70) | $ (0.42) |
| Weighted average common shares outstanding, basic and diluted | 161,231 | 160,011 |

[1] Includes the following stock-based compensation expense

| | | |
|---|---|---|
| Cost of product sales, license fees and royalties | $ 323 | $ 163 |
| Research and development | $ 5,464 | $ 4,830 |
| Selling, general and administrative | $ 9,176 | $ 8,191 |

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

| | March 31, 2022 | December 31, 2021 |
|---|---|---|
| | (unaudited) | |
| **Assets** | | |
| Cash, cash equivalents and investment securities | $ 445,977 | $ 520,706 |
| Accounts receivable, net | 62,713 | 64,366 |
| Interest and other receivables | 769 | 978 |
| Inventory | 7,009 | 7,881 |
| Prepaid expenses | 25,755 | 23,892 |
| Total current assets | 542,223 | 617,823 |
| Property and equipment, net | 7,531 | 8,047 |
| Operating lease right-of-use assets | 58,186 | 58,268 |
| Restricted cash | 5,770 | 5,770 |
| Long-term inventory | 6,205 | 6,217 |
| Other assets | 4,336 | 3,997 |
| Total assets | $ 624,251 | $ 700,122 |
| **Liabilities and stockholders' equity** | | |
| Accounts payable | $ 10,768 | $ 6,876 |
| Accrued liabilities | 108,835 | 89,192 |
| Total current liabilities | 119,603 | 96,068 |
| Operating lease liabilities | 55,478 | 56,126 |
| Other long-term liabilities | 4,373 | 7,034 |
| Total liabilities | 179,454 | 159,228 |
| Total stockholders' equity | 444,797 | 540,894 |
| Total liabilities and stockholders' equity | $ 624,251 | $ 700,122 |

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