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): April 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** **(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 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))

Securitiesregistered 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 7.01 Regulation FD Disclosure.

On April 5, 2021, Acadia Pharmaceuticals Inc. (the "Company") issued a press release announcing the receipt of a complete response letter from the U.S. Food and Drug Administration (the "FDA") regarding the Company's supplemental new drug application for pimavanserin for the treatment of hallucinations and delusions associated with dementia-related psychosis and held a conference call. A copy of the Company's press release dated April 5, 2021 is attached as Exhibit 99.1 and is incorporated herein by reference. A copy of the material presented during the Company's conference call is attached as Exhibit 99.2 and is incorporated herein by reference. The information in this Item 7.01 and Exhibits 99.1 and 99.2 is being furnished to the Securities and Exchange Commission (the "Commission") 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 the liabilities of that Section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, regardless of any general incorporation language in such filing, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On April 5, 2021, the Company issued a press release announcing the receipt of a complete response letter from the FDA regarding the Company's supplemental new drug application for pimavanserin for the treatment of hallucinations and delusions associated with dementia-related psychosis and held a conference call. A copy of the Company's press release dated April 5, 2021 is attached as Exhibit 99.1 and is incorporated herein by reference. A copy of the material presented during the Company's conference call is attached as Exhibit 99.2 and is incorporated herein by reference. The information in this Item 8.01 and Exhibits 99.1 and 99.2 is being furnished to the Commission and shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act, regardless of any general incorporation language in such filing, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release dated April 5, 2021
99.2	Regulatory Update on DRP sNDA dated April 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: April 5, 2021

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

Exhibit 99.1

Acadia Pharmaceuticals Receives Complete Response Letter from U.S. FDA for Supplemental New Drug Application for Pimavanserin for the Treatment of Hallucinations and Delusions Associated with Dementia-Related Psychosis

- Conference call and webcast to be held today at 8:00 a.m. Eastern Time

SAN DIEGO April 5, 2021 – Acadia Pharmaceuticals Inc. (Nasdaq: ACAD) today announced that the Company has 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 FDA issued a CRL to indicate that they have completed their review of the application and has determined that the application cannot be approved in its present form.

Despite prior agreements with the Division of Psychiatry regarding the pivotal Phase 3 HARMONY study design targeting a broad DRP patient population analyzed as a single group, the Division, in the CRL, cited a lack of statistical significance in some of the subgroups of dementia, and insufficient numbers of patients with certain less common dementia subtypes as lack of substantial evidence of effectiveness to support approval.

The DRP pivotal HARMONY study met its prespecified primary and secondary endpoints with robust and persuasive clinical and statistical superiority of pimavanserin over placebo, which was a prospectively agreed prerequisite for the DRP indication. Statistical separation by dementia subgroups and certain minimum numbers of patients with specific subtypes were not among the prespecified requirements.

“Acadia stands behind the robustly positive results from the pivotal Phase 3 HARMONY study and the prospectively agreed trial design and criteria for establishing efficacy in DRP. Over the entire course of the review, the Division did not raise any concerns regarding the agreed upon study design, including the issues raised in the CRL,” said Steve Davis, Chief Executive Officer of Acadia. “We will immediately request a Type A meeting to work with the FDA to address the CRL and determine an expeditious path forward for the approval of pimavanserin in DRP.”

The Division also stated in the CRL that it considers the Phase 2 Alzheimer’s disease psychosis study -019, a supportive study in the sNDA filing, to not be adequate and well controlled, citing that it was a single center study with no type I error control of secondary endpoints in which certain protocol deviations occurred. The Company believes these observations impact neither the positive results on the study’s primary endpoint, nor the study’s overall conclusions of efficacy.

There were no safety issues or concerns raised in the CRL.

sNDA Submission for Dementia-Related Psychosis

The sNDA submission of pimavanserin for the treatment of hallucinations and delusions associated with DRP was supported by results from the pivotal Phase 3 HARMONY study, which met its primary endpoint, demonstrating that pimavanserin significantly reduced the risk

of relapse of psychosis by 2.8 fold compared to placebo (hazard ratio = 0.353; one-sided p=0.0023). Pimavanserin also met the key secondary endpoint in the study, significantly reducing the risk of discontinuation for any reason by 2.2 fold compared to placebo (hazard ratio =0.452, one-sided p=0.0024). The sNDA also included positive efficacy results from two additional placebo-controlled studies, both of which met their respective primary endpoints: The Phase 2 (-019) study in patients with Alzheimer's disease psychosis and the Phase 3 (-020) study in patients with Parkinson's disease psychosis. In addition, the sNDA included a large safety database from completed and ongoing studies representing over 1,500 patients with neurodegenerative disease.

Conference Call and Webcast Information

Acadia management will discuss today's announcement via conference call and webcast at 8:00 a.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 6894834). A telephone replay of the conference call may be accessed through April 19, 2021 by dialing 855-859-2056 for callers in the United States or Canada and 404-537-3406 for international callers (reference passcode 6894834). 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 through May 3, 2021.

About Dementia-Related Psychosis

Approximately 8 million people in the United States are living with dementia, a condition with a core feature of declining cognition (changes in memory, decision-making abilities, language, etc.) resulting in functional impairment. Dementia is a manifestation of an underlying condition which is often progressive and neurodegenerative in nature. In addition to cognitive decline, dementing illnesses almost universally lead to neuropsychiatric symptoms, including hallucinations, delusions, and changes in behavior.

It is estimated that 2.4 million Americans (or 30% of people with dementia) experience dementia-related hallucinations and delusions. These symptoms may be frequent and severe and may recur over time. A hallucination is defined as a perception-like experience that occurs without an external stimulus and is sensory (seen, heard, felt, tasted, sensed) in nature. A delusion is defined as a false, fixed belief that is resolutely held despite evidence to the contrary. Dementia-related psychosis occurs in many types of dementia, including Alzheimer's disease, dementia with Lewy bodies, Parkinson's disease dementia, vascular dementia, and frontotemporal dementia. Serious consequences have been associated with psychosis in patients with dementia, such as repeated hospital admissions, increased likelihood of nursing home placement, faster progression of dementia, and increased risk of morbidity and mortality.

About 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 dementia-related psychosis. In addition, Acadia is developing pimavanserin in other neuropsychiatric conditions.

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.

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 regarding the timing of future events. 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 risks and uncertainties inherent in drug development, approval and commercialization. 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.

Important Safety Information and Indication for NUPLAZID® (pimavanserin)

Indication

NUPLAZID is indicated for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis.

Important Safety Information

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

- **Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death.**
- **NUPLAZID is not approved for the treatment of patients with dementia-related psychosis unrelated to the hallucinations and delusions associated with Parkinson's disease psychosis.**

- **Contraindication:** NUPLAZID is contraindicated in patients with a history of a hypersensitivity reaction to pimavanserin or any of its components. Rash, urticaria, and reactions consistent with angioedema (e.g., tongue swelling, circumoral edema, throat tightness, and dyspnea) have been reported.
- **Warnings and Precautions:** QT Interval Prolongation
  - NUPLAZID prolongs the QT interval. The use of NUPLAZID should be avoided in patients with known QT prolongation or in combination with other drugs known to prolong QT interval including Class 1A antiarrhythmics or Class 3 antiarrhythmics, certain antipsychotic medications, and certain antibiotics.
  - NUPLAZID should also be avoided in patients with a history of cardiac arrhythmias, as well as other circumstances that may increase the risk of the occurrence of torsade de pointes and/or sudden death, including symptomatic bradycardia, hypokalemia or hypomagnesemia, and presence of congenital prolongation of the QT interval.
- **Adverse Reactions:** The common adverse reactions (≥2% for NUPLAZID and greater than placebo) were peripheral edema (7% vs 2%), nausea (7% vs 4%), confusional state (6% vs 3%), hallucination (5% vs 3%), constipation (4% vs 3%), and gait disturbance (2% vs <1%).
- **Drug Interactions:**
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole) increases NUPLAZID exposure. Reduce NUPLAZID dose to 10 mg taken orally as one tablet once daily.
  - Coadministration with strong or moderate CYP3A4 inducers reduces NUPLAZID exposure. Avoid concomitant use of strong or moderate CYP3A4 inducers with NUPLAZID.

Dosage and Administration

Recommended dose: 34 mg capsule taken orally once daily, without titration.

NUPLAZID is available as 34 mg capsules and 10 mg tablets.
Please read the full Prescribing Information including Boxed WARNING.

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Exhibit 99.2

ACADIA

Regulatory Update on DRP sNDA

April 5, 2021

Agenda

Introduction	**Mark Johnson** | Vice President, Investor Relations
CEO Opening Remarks	**Steve Davis** | Chief Executive Officer
Discussion	**Serge Stankovic, M.D., M.S.P.H** | President
CEO Closing Remarks	**Steve Davis** | Chief Executive Officer
Q&A	**Steve Davis** | Chief Executive Officer **Serge Stankovic, M.D., M.S.P.H** | President **Elena Ridloff** | Chief Financial Officer

Forward-Looking Statements

This presentation contains forward-looking statements. These statements relate to future events and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed in or implied by such forward-looking statements. Each of these statements is based only on current information, assumptions and expectations that are inherently subject to change and involve a number of risks and uncertainties. Forward-looking statements include, but are not limited to, statements about (i) plans for, including timing and progress of commercialization of, NUPLAZID® or for the clinical development of our product candidates, including pimavanserin and trofinetide; (ii) benefits to be derived from and efficacy of our product candidates, including the use of pimavanserin in dementia-related psychosis, schizophrenia or other neurological or psychiatric indications, potential advantages of NUPLAZID versus existing antipsychotics or antidepressants, and expansion opportunities for NUPLAZID; (iii) estimates regarding the prevalence of Parkinson's disease psychosis, dementia-related psychosis, schizophrenia and the potential use of trofinetide in Rett syndrome; (iv) potential markets for any of our products, including NUPLAZID and trofinetide; (v) our estimates regarding our future financial performance, cash position or capital requirements; and (vi) currently anticipated impacts of COVID-19 on Acadia's business, including its commercial sales operations, current and planned clinical trials, supply chain, and guidance for full-year 2021 NUPLAZID net sales and certain expense line items.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions (including the negative thereof) intended to identify forward-looking statements. Given the risks and uncertainties, you should not place undue reliance on these forward-looking statements. For a discussion of the risks and other factors that may cause our actual results, performance or achievements to differ, please refer to our annual report on Form 10-K for the year ended December 31, 2020 as well as our subsequent filings with the SEC. The forward-looking statements contained herein are made as of the date hereof, and we undertake no obligation to update them for future events.

Opening Remarks

Steve Davis

Chief Executive Officer

Opening Remarks

ACADIA

Prior Agreements between Acadia and the Division of Psychiatry:

- Agreement on pivotal HARMONY Phase 3 study design
- Agreement on primary endpoint of HARMONY as risk of relapse of psychosis of pimavanserin compared to placebo in the broad DRP patient population to be analyzed as a single group
- Agreement to a representative sample of various dementia subtypes and that the study would not be powered for statistical significance by subgroup

Despite these agreements, in the CRL, the Division of Psychiatry cited as lack of substantial evidence of effectiveness to support approval:

- Lack of statistical significance in some of the subgroups of dementia, and
- Insufficient numbers of patients with certain less common dementia subtypes

Statistical separation by dementia subgroups and certain minimum numbers of patients with specific subtypes were not among the prespecified requirements with the Division

Pivotal HARMONY Study for DRP

ACADIA

1. Highly statistically significant results in pivotal Phase 3 HARMONY study

2. Clinically meaningful results in pivotal Phase 3 HARMONY study

3. Delivered persuasive results from the agreed upon pivotal study design targeting a broad DRP patient population analyzed as a single group

NUPLAZID (pimavanserin) is only approved in the U.S. by the FDA for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis.
Provided April 5, 2021 as part of an oral presentation and is qualified by such; contains forward-looking statements; actual results may vary materially; Acadia disclaims any duty to update.

Discussion

Serge Stankovic

President

Pivotal HARMONY Study Results

ACADIA

"If you wish to rely on a single well-controlled study for your sNDA filing, the findings must be very persuasive. This means statistically significant with a very small probability of Type I error and a finding that is clinically meaningful." ***– FDA, End-of-Phase 2 Meeting***

Pivotal HARMONY (-045) Results

1

26-Week Double-Blind Efficacy Results:

- *Pimavanserin significantly reduced the risk of relapse of psychosis by 2.8 fold (Hazard Ratio=0.353, one-sided p=0.0023)*
- *Pimavanserin met the key secondary endpoint by significantly reducing risk of discontinuation for any reason by 2.2 fold (Hazard Ratio=0.452, one-sided p=0.0024)*

2

12-Week Open-Label Efficacy Results:

- *Pimavanserin treatment showed a meaningful reduction of the symptoms and stabilization of psychosis across all dementia subtypes evaluated*
- *~62% of patients met the pre-specified response criteria and were randomized*

3

Safety and Tolerability Results:

- *Pimavanserin was well-tolerated in elderly patients with dementia-related psychosis over 9-month study*
- *Patients receiving pimavanserin treatment had no worsening in cognition or motor function, as measured by MMSE[1] and ESRS-A[2] scores*

[1]MMSE = Mini-Mental State Examination; [2]ESRS-A = Extrapyramidal Symptom Rating Scale-A

Agreement on Pivotal Study Design

ACADIA

Agreed with the Division	Pivotal Study Results	CRL Response
"…the Division agreed that the randomized withdrawal trial as described in the meeting briefing package would be acceptable as a well-controlled trial for submission of a sNDA for the indication of hallucinations and delusions associated with dementia-related psychosis." ***– FDA, End-of-Phase 2 Meeting***	Highly ***statistically significant*** and ***clinically meaningful*** study results according to the pre-specified primary and secondary outcome measures. Consistent and sustained response across subtypes in open-label period. Well-tolerated with no negative impact on cognitive functioning or motor symptoms.	*"The sNDA submission does not provide substantial evidence of effectiveness to support the approval of pimavanserin for the hallucinations and delusions associated with DRP."* *"…the results from the Alzheimer's disease subgroup were not nominally significant."* ***– FDA, Complete Response Letter***

Agreement on Target Patient Population

ACADIA

Agreed with the Division	Pivotal Study Results	CRL Response
"We agree that treatment of hallucinations and delusions in dementia-related psychosis is a potentially approvable indication. We agree that dementias need not be etiologically related for the common symptoms of psychosis to respond to pimavanserin." – ***FDA, End-of-Phase 2 Meeting***	Highly ***statistically significant*** and ***clinically meaningful*** study results according to the pre-specified primary and secondary outcome measures. Consistent and sustained response across subtypes in open-label period. Well-tolerated with no negative impact on cognitive functioning or motor symptoms.	*"Findings from Study -045 suggest a differential response to pimavanserin across dementia subtypes, questioning whether 'dementia-related psychosis' is a useful construct for a potential indication for pimavanserin."* – ***FDA, Complete Response Letter***

Closing Remarks

Steve Davis

Chief Executive Officer

Conclusion and Next Steps

ACADIA

1. Agreed with the Division of Psychiatry that a single, positive, randomized withdrawal study with very persuasive efficacy would be sufficient for approval in DRP

2. Delivered the highly statistically significant and clinically meaningful results from the agreed upon pivotal Phase 3 HARMONY study

3. CRL based on analyses by dementia subgroup that the agreed upon pivotal program was not intended, designed, or powered to demonstrate

We strongly disagree with the Division of Psychiatry's decision and will immediately request a Type A meeting

Q&A Session