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): September 9, 2019

ACADIA Pharmaceuticals Inc.
(Exact name of registrant as specified in its charter)

Delaware	000-50768	06-1376651
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(IRS Employer Identification No.)

3611 Valley Centre Drive, Suite 300 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 8.01 Other Events.

On September 9, 2019, the Company announced that its Phase 3 HARMONY study, a double-blind, placebo-controlled relapse prevention study of pimavanserin for the treatment of hallucinations and delusions associated with dementia-related psychosis, met its primary endpoint, demonstrating a highly statistically significant longer time to relapse of psychosis with pimavanserin compared to placebo in a planned interim efficacy analysis. Upon the recommendation of the study's independent data monitoring committee, which met to review the data from the planned interim efficacy analysis, the study will now be stopped early based on pre-specified stopping criteria requiring a one-sided p-value less than 0.0033 on the study's primary endpoint.

The Company is planning to meet with the FDA regarding a supplemental NDA submission in 2020 and the results from the HARMONY study will be submitted for presentation at upcoming medical meetings.

The HARMONY study included a 12-week open-label stabilization period during which patients with dementia-related psychosis were treated with pimavanserin 34 mg once daily. Dose reduction to 20 mg once daily was allowed if clinically justified within the first four weeks. Following the 12-week stabilization period, patients who met pre-specified criteria for treatment response were then randomized into the double-blind period of the study to continue their pimavanserin dose (34 mg or 20 mg per day) or switched to placebo and followed for up to 26 weeks or until a relapse of psychosis occurred. The primary endpoint in the study was time to relapse in the double-blind period. Relapse (significant worsening of dementia-related psychosis after prior stabilization) was defined in the study by one or more of the following: hospitalization due to dementia-related psychosis, significant deterioration of dementia-related symptoms on clinical scales, withdrawal from the study due to lack of efficacy, or the use of an off-label antipsychotic medication for the treatment of dementia-related delusions and/or hallucinations. All potential relapses and discontinuations in the double-blind portion of the study were adjudicated by an independent adjudication committee to determine if protocol defined relapse criteria were met.

A copy of ACADIA's press release issued September 9, 2019 is furnished herewith as Exhibit 99.1.

Forward-Looking Statements

Statements in this Current Report that are not strictly historical in nature are forward-looking statements. These statements include, but are not limited to, statements related to: intended activities with respect to the HARMONY study following the interim analysis, expected timelines with respect to full data from the HARMONY study and the Company's planned engagement with the FDA. 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, 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 the Company's annual report on Form 10-K for the year ended December 31, 2018 as well as its 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 the Company undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof, except as required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1	Press release dated September 9, 2019
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.

Date: September 9, 2019

ACADIA Pharmaceuticals Inc.

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

Exhibit 99.1

ACADIA Pharmaceuticals Announces Pivotal Phase 3 HARMONY Trial Stopped Early for Positive Efficacy as Pimavanserin Meets the Primary Endpoint in Patients with Dementia-Related Psychosis

- Pimavanserin achieved robust statistical superiority over placebo in time to relapse of dementia-related psychosis at planned interim efficacy analysis

- Pimavanserin has the potential to be the first FDA-approved drug for the treatment of dementia-related psychosis

- Approximately 1.2 million patients in the United States are diagnosed with dementia-related psychosis

- Conference call and webcast to be held today at 8:30 a.m. Eastern Time

SAN DIEGO – September 9, 2019 – ACADIA Pharmaceuticals Inc. (Nasdaq: ACAD) today announced that its Phase 3 HARMONY study, a double-blind, placebo-controlled relapse prevention trial evaluating pimavanserin for the treatment of dementia-related psychosis, met its primary endpoint, demonstrating a highly statistically significant longer time to relapse of psychosis with pimavanserin compared to placebo in a planned interim efficacy analysis.

Upon the recommendation of the study's independent data monitoring committee, which met to review the data from the planned interim efficacy analysis, the study will now be stopped early based on pre-specified stopping criteria requiring a one-sided p-value less than 0.0033 on the study's primary endpoint.

The Company is planning to meet with the FDA regarding a supplemental NDA submission in 2020 and the results from the HARMONY study will be submitted for presentation at upcoming medical meetings.

The FDA previously granted Breakthrough Therapy Designation for pimavanserin for the treatment of dementia-related psychosis. No drug is approved by the FDA for the treatment of dementia-related psychosis.

"Psychosis adds dramatically to the marked burden that dementia patients already carry and is one of the most challenging-to-manage aspects of the disease for caregivers," said Jeffrey Cummings, M.D., Sc.D., Director Emeritus of Cleveland Clinic Lou Ruvo Center for Brain Health in Las Vegas. "With no approved treatment options available today for dementia-related psychosis, the pimavanserin study results represent a meaningful advance that will potentially bring us a much

needed therapy for this debilitating disease."

"We are very excited that today's results bring us one step closer to the potential of offering patients with dementia-related psychosis a critically needed treatment option," said Serge Stankovic, M.D., M.S.P.H., ACADIA's President. "We look forward to speaking with the FDA about a supplemental new drug application to support pimavanserin for the treatment of dementia-related psychosis. I want to thank all of the patients, their families, and the investigators for their participation in this important study."

About the HARMONY Study

HARMONY is a Phase 3 study designed to evaluate the efficacy and safety of pimavanserin for the treatment of delusions and hallucinations associated with dementia-related psychosis across a broad population of patients with the most common subtypes of dementia including: Alzheimer's disease, dementia with Lewy bodies, Parkinson's disease dementia, vascular dementia, and frontotemporal dementia spectrum disorders.

The HARMONY study included a 12-week open-label stabilization period during which patients with dementia-related psychosis were treated with pimavanserin 34 mg once daily. Dose reduction to 20 mg once daily was allowed if clinically justified within the first four weeks. Following the 12-week stabilization period, patients who met pre-specified criteria for treatment response were then randomized into the double-blind period of the study to continue their pimavanserin dose (34 mg or 20 mg per day) or switched to placebo and followed for up to 26 weeks or until a relapse of psychosis occurred. The primary endpoint in the study was time to relapse in the double-blind period.

Relapse (significant worsening of dementia-related psychosis after prior stabilization) was defined in the study by one or more of the following: hospitalization due to dementia-related psychosis, significant deterioration of dementia-related symptoms on clinical scales, withdrawal from the study due to lack of efficacy, or the use of an off-label antipsychotic medication for the treatment of dementia-related delusions and/or hallucinations. All potential relapses and discontinuations in the double-blind portion of the study were adjudicated by an independent adjudication committee to determine if protocol defined relapse criteria were met.

Conference Call and Webcast Information

ACADIA will discuss today's announcement from its Phase 3 trial of pimavanserin for the treatment of patients with dementia-related psychosis via conference call and webcast today at 8:30 a.m. Eastern Time. The conference call can be accessed by dialing 855-638-4820 for participants in the U.S. or Canada and 443-877-4067 for international callers (reference passcode 9785159). A telephone replay of the conference call may be accessed through September 16, 2019 by dialing 855-859-2056 for callers in the U.S. or Canada and 404-537-3406 for international callers (reference passcode 9785159). The conference call will also be webcast live on ACADIA's website, www.acadia-pharm.com, in the investors section and will be archived there until October 9, 2019.

About Dementia-Related Psychosis

Around 8 million people in the United States are living with dementia and studies suggest that approximately 30% of dementia patients, or 2.4 million people, have psychosis, commonly consisting of delusions and hallucinations[1,2]. Dementia-related psychosis includes psychosis in Alzheimer's disease, dementia with Lewy bodies, Parkinson's disease dementia, vascular dementia, and frontotemporal dementia. Serious consequences have been associated with severe or persistent psychosis in patients with dementia such as repeated hospital admissions, increased likelihood of nursing home placement, progression of dementia, and increased risk of morbidity and mortality[3].

About 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 psychosis, schizophrenia, depression and other neuropsychiatric disorders. In vitro, pimavanserin demonstrated no appreciable binding affinity for dopamine (including D2), histamine, muscarinic, or adrenergic receptors. ACADIA is evaluating pimavanserin in an extensive clinical development program across multiple indications with significant unmet need including dementia-related psychosis, adjunctive major depressive disorder, and the negative symptoms of schizophrenia. 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, schizophrenia or major depressive disorder.

About ACADIA Pharmaceuticals

ACADIA is a biopharmaceutical company focused on the development and commercialization of innovative medicines to address unmet medical needs in central nervous system disorders. ACADIA has developed and commercialized the first and only medicine approved for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis. ACADIA also has ongoing clinical development efforts in additional areas with significant unmet need, including dementia-related psychosis, major depressive disorder, the negative symptoms of schizophrenia, and Rett syndrome. This press release and further information about ACADIA can be found at: www.acadia-pharm.com.

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: intended activities with respect to the HARMONY study following the interim analysis, expected timelines with respect to full data from the HARMONY study and the Company's planned engagement with the FDA. 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, 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, 2018 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)

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.

- **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 most 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.

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

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 see the full Prescribing Information including **Boxed WARNING** for NUPLAZID.

References
[1] 2017 Alzheimer's Disease Facts and Figures and ACADIA market research
[2]Plassman BL, et al. Prevalence of dementia in the United States: the Aging Demographics, and Memory study. *Neuroepidemiology*. 2007;29(1-2):125-132.
[3]Connors MH et al. *Am J Geriatr Psychiatry* 2018;26(3). Peters ME et al. *Am J Psychiatry* 2015;172(5). Haupt M et al. *Int J Geriatr Psychiatry* 1996;11(11). Naimark D et al. *J Am Geriatr Soc* 1996;44(3). Stern Y et al. *Neurology* 1994;44(12).

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