

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 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 6, 2024

**ANNOVIS BIO, INC.**  
(Exact Name of Registrant as Specified in Charter)

Delaware  
(State or Other Jurisdiction  
of Incorporation)

001-39202  
(Commission  
File Number)

26-2540421  
(I.R.S. Employer  
Identification No.)

101 Lindenwood Drive, Suite 225  
Malvern, PA 19355  
(Address of Principal Executive Offices, and Zip Code)

(484) 875-3192  
Registrant's Telephone Number, Including Area Code

Not Applicable  
(Former Name or Former Address, if Changed Since Last Report)

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	ANVS	New York Stock Exchange

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 (see General Instruction A.2. below):

- Written communication 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 communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communication pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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 May 6, 2024, Annovis Bio, Inc. (the “Company”) issued a press release dated May 6, 2024 which is being furnished as Exhibit 99.1 hereto.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

<b>Exhibit No.</b>	<b>Description</b>
<a href="#">99.1</a>	<a href="#">Press Release Dated May 6, 2024</a>
104	Cover Page Interactive Data File

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**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.

**ANNOVIS BIO, INC.**

Date: May 6, 2024

By: /s/ Maria Maccellini

Name: Maria Maccellini

Title: President and Chief Executive Officer

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## Annovis Bio CEO Maria Maccacchini Issues Letter to Stockholders

**MALVERN, Pa. -- May 6, 2024** -- Annovis Bio, Inc. (NYSE: ANVS) (“Annovis” or the “Company”), a clinical-stage drug platform company developing novel therapies for neurodegenerative diseases, announced that Maria Maccacchini, Founder, President, and CEO of Annovis, issued a letter to stockholders providing a review of Phase II/III data from its Alzheimer’s study and sharing next steps.

Dear Friends,

The last few days have been very difficult. I received a lot of emails and phone calls that often expressed anger, uncertainty, and disappointment. Additionally, our results were questioned and criticized. This reaction not only caused a drastic drop in our share price, but, more importantly, it saddened the Annovis team. We are determined to develop a drug that treats Alzheimer’s (AD) and Parkinson’s diseases (PD) and makes the life of the afflicted people and their caretakers easier. However, every setback makes it harder to reach this goal.

At Annovis, we hold rigorous science, open communication, and transparency seriously, and it is our responsibility to conduct a clinical study in conformance with FDA guidelines and to the highest standards possible. In science, results are often less than perfect, but they pave the way for a better plan when designing and executing the next steps.

The Phase II/III study provided us with valuable information for an improved Phase III pivotal trial. First, we will prescreen patients for plasma AD biomarkers to confirm the diagnosis. Second, we will only enroll patients with early and mild Alzheimer’s (MMSE 21-28), the subpopulation which showed the highest level of improvement after buntanetap, as seen from our completed AD studies (Table 1).

Study	AD patient	# Patients	Endpoint	Duration	Drug vs Baseline	Drug vs Placebo
Phase IIa; 2021	MMSE 18-28	14	ADAS-Cog11	1 month	-4.4	-3.2
Phase II/III; 2024	MMSE 21-24	90	ADAS-Cog11	3 months	-3.3	-2.36
Phase II/III; 2024	MMSE 14-20	112	ADAS-Cog11	3 months	-0.65	1.79

Table 1. Summary of cognitive response to buntanetap at different disease stages measured in completed AD studies conducted by Annovis. The table clearly shows a strong response in patients with early AD (MMSE 18-28 and MMSE 21-24), while in moderate AD patients (MMSE 14-20), the response is obscured by high placebo effect.

The goal of the Phase II/III trial was to learn about the breadth of our drug’s efficacy and to obtain information for a pivotal disease-modifying study. This goal was achieved. We believe that the FDA will accept buntanetap for symptomatic relief and will allow us to continue with the next pivotal Phase III study for disease-modification.

## **About Buntanetap**

Buntanetap (formerly known as Posiphen or ANVS401) attacks neurodegeneration by inhibiting the formation of multiple neurotoxic proteins - amyloid beta, tau, alpha synuclein, and TDP43 - thereby improving synaptic transmission, axonal transport and neuroinflammation. Dysregulation of these pathways has been shown to be the cause of nerve cell degeneration and ultimately death. By attacking these pathways, buntanetap has the ability to reverse neurodegeneration in Alzheimer's, Parkinson's, and other neurodegenerative diseases.

## **About Annovis Bio, Inc.**

Headquartered in Malvern, Pennsylvania, Annovis Bio, Inc. is a clinical-stage, drug platform company addressing neurodegeneration, such as Alzheimer's Disease (AD), Parkinson's Disease (PD), and other chronic neurodegenerative diseases. The company believes it is the only company developing a drug for both AD and PD designed to inhibit more than one neurotoxic protein to restore axonal and synaptic activity. By improving brain function, the Company's goal is to treat memory loss and dementia associated with AD as well as body and brain dysfunction associated with PD. For more information about Annovis Bio, please visit the Company's website [www.annovisbio.com](http://www.annovisbio.com) and follow us on LinkedIn and Twitter.

## **Forward-Looking Statements**

This press release contains "forward-looking" statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. The Company advises caution in reliance on forward-looking statements. Forward-looking statements include, without limitation, the Company's plans related to clinical trials. These statements involve known and unknown risks, uncertainties and other factors that may cause actual results to differ materially from those implied by forward-looking statements, including regarding patient enrollment, the effectiveness of buntanetap and the timing, effectiveness, and anticipated results of the Company's clinical trials evaluating the efficacy, safety, and tolerability of buntanetap. See also additional risk factors set forth in the Company's periodic filings with the SEC, including, but not limited to, those risks and uncertainties listed in the section entitled "Risk Factors," in the Company's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q filed with the SEC. All forward-looking statements in this press release are based on information available to the Company as of the date of this filing. The Company expressly disclaims any obligation to update or alter its forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

## **Investor Contacts:**

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