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 9, 2024

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

Delaware	**001-39202**	**26-2540421**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(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 9, 2024, Annovis Bio, Inc. (the "Company") issued a press release dated May 9, 2024 which is being furnished as Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release Dated May 9, 2024
104	Cover Page Interactive Data File

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 9, 2024

By: /s/ Maria Maccecchini
Name: Maria Maccecchini
Title: President and Chief Executive Officer

Exhibit 99.1

ANNOVIS ANNOUNCES UNBLINDING OF THE BUNTANETAP PHASE III DATA IN PARKINSON'S DISEASE

MALVERN, Pa. -- **May 9, 2024** -- Annovis Bio, Inc. (NYSE: ANVS) ("Annovis" or the "Company"), a clinical-stage drug platform company developing novel therapies for neurodegenerative diseases, today announced successful completion of data cleaning for its Phase III study of buntanetap in patients with early Parkinson's disease (PD). Topline efficacy data is expected in June.

The Phase III study was completed in 4Q 2023 with an original plan for data announcement in 1Q 2024, however the Company faced a delay in the process of data cleaning beyond the original prognosis. Maria Maccecchini, Ph.D., Founder, President, and CEO of Annovis, explains in detail the reason behind this delay:

"When we reached the point of unblinding the data for the PD Phase III study, we discovered an unexpected issue: too many plasma samples showed no presence of buntanetap. We were expecting 33% blank samples from the placebo group, but we saw over 50% blank samples. We were afraid that we had mixed up bottles and that patients weren't given what they were supposed to. If that had happened, the study would have been worthless. We promptly started searching for a possible explanation at every step of the way. We checked the content of the bottles – correct. We checked the distribution of the bottles – correct. We checked the labeling of the plasma samples – correct. We checked the distribution of the plasma samples – correct. So, we were left with the pharmacokinetic (PK) measurements. PK is measured by LC-MS/MS with a very expensive set of equipment under GLP, GCP, GMP, and is regulated by very strict FDA rules. It turns out that the group, which was evaluating the PK, modified the method, unfortunately affecting the measurements. We repeated the PK of the same samples and obtained an expected 33% of blank samples accounting for placebo.

The whole process took us 2 months, which caused the delay in data announcement. However, due to our effort and immediate actions, we are now confident and ready to evaluate the data for the public and the FDA and report topline results in June.

Thank you very much for your understanding and patience."

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. It is believed to be 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 on Annovis Bio, please visit the Company's website www.annovisbio.com and follow us on LinkedIn and X (formerly known as 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 Contact:

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