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): October 10, 2023

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.)

1055 Westlakes Drive, Suite 300
Berwyn, PA 19312
(Address of Principal Executive Offices, and Zip Code)

(610) 727-3913
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 8.01 Other Events.

On October 12, 2023, the Company issued a press release announcing the positive interim independent analysis for statistical power in its Alzheimer's study. A copy of this press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release, dated October 12, 2023.
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.

ANNOVIS BIO, INC.

Date: October 12, 2023

By: /s/ Henry Hagopian, III
Name: Henry Hagopian, III
Title: Chief Financial Officer

Exhibit 99.1

ANNOVIS BIO ANNOUNCES POSITIVE INTERIM INDEPENDENT ANALYSIS FOR STATISTICAL POWER IN ITS ALZHEIMER'S STUDY

October 12, 2023

Pre-specified, blinded interim analysis for sample size re-estimation indicates that the ongoing Phase 2/3 study in Alzheimer's Disease (AD) is sufficiently powered to continue as planned without any additional patients.

BERWYN, Pa., October 12, 2023 /PRNewswire/ -- Annovis Bio, Inc. (NYSE: ANVS) ("Annovis" or the "Company"), a clinical-stage drug platform company addressing neurodegenerative diseases, today announced that the independent statistical group concluded that its Phase 2/3 AD study was sufficiently powered to continue as originally planned without the addition of patients. This phase 2/3 AD study is designed to enroll a total of 320 mild to moderate AD patients, who are randomly assigned to receive 7.5, 15, 30 mg of buntanetap or placebo once per day. The trial's co-primary endpoints are the change from baseline to the end of treatment of Alzheimer's Disease Assessment Scale-Cognitive Subscale 11 (ADAS-Cog11) and Alzheimer's Disease Cooperative Study Clinician's Global Impression of Change (ADCS-CGIC), which assess cognition and activities of daily living.

The Company has received the results of the pre-planned interim analysis conducted by an independent data analytics provider. The interim analysis was based on 107 patients at 6 weeks from all cohorts collectively and showed that the AD trial should continue as planned with the same trial size to maintain the statistical power for both co-primary endpoints.

The Company remains blinded to the Phase 3 trial and does not have safety or efficacy data from the trial. A separate safety interim analysis is in process and we expect that interim analysis to be released in two weeks.

Maria L. Maccecchini, Ph.D., Founder, President, and CEO of Annovis, commented: "Although we remain blinded to the data, results from this interim analysis supports our original statistical powering for enrolling 320 patients into the Phase 2/3 Alzheimer's study. Therefore, sample size re-estimation for the study is not necessary, which in our view, may signal an emerging positive treatment effect in patients receiving buntanetap versus those receiving placebo after just 6 weeks of treatment. While the interim analysis does not mean that the trial will necessarily be successful, it does mean that the trial is powered for potential success."

Update and projections of our ongoing activities:

Alzheimer's disease

- to date, 230 patients have been enrolled and 62 have finished the study,
- safety interim analysis, conducted by the DSMB on October 18, will be released the week of October 23,
- full enrollment anticipated in November,
- completion of treatment expected in February 2024,
- phase 2/3 data expected in March 2024.

Parkinson’s disease

- to date, 305 patients have finished the study,
- completion of study expected by the end of November,
- phase 3 data expected in January 2024.

In addition to the ongoing clinical studies, we are also excited about the novel crystal form of buntanetap - ANVS402. We expect to discuss with the FDA the transition buntanetap to ANVS402 and the development of the new form. The bridge studies are expected to be completed in Q1 2024.

As we move forward with our advanced, clinical-stage AD and PD programs, we hope to demonstrate buntanetap’s unique ability to inhibit the accumulation of pro-inflammatory, neurotoxic proteins and potential to address unmet medical need across a number of neurodegenerative conditions and diseases.

About Buntanetap

Buntanetap (previously known as ANVS401 or Posiphen) is an investigational, oral translational inhibitor of neurotoxic aggregating proteins (TINAPs), which mode of action is thought to lead to a lower level of neurotoxic proteins and consequently less toxicity in the brain. In a Phase 2a clinical trial in AD and PD patients, buntanetap was shown to be generally well-tolerated , and its pharmacokinetics were found to be in line with levels measured earlier in humans, meeting both the primary and secondary endpoints. Additionally, exploratory endpoints were also met, as treatment with buntanetap resulted in statistically significant improvement in motor function in PD patients and cognition in AD patients. Presently buntanetap is being studied in a Phase 3 early PD study and in a Phase 2/3 study in AD patients.

About Annovis Bio, Inc.

Headquartered in Berwyn, Pennsylvania, Annovis Bio, Inc. (Annovis) is a clinical-stage, drug platform company addressing neurodegeneration, such as Alzheimer's disease (AD), Parkinson's disease (PD), and other chronic neurodegenerative diseases. We believe that we are the only company developing a drug for AD and PD that inhibits more than one neurotoxic protein and, thereby, improves the information highway of the nerve cell, known as axonal transport. When this information flow is impaired, the nerve cell gets sick and dies. Annovis conducted two Phase 2 studies: one in AD patients and one in both AD and PD patients. In the AD/PD study buntanetap showed improvements in cognition and memory in AD as well as body and brain function in PD patients.

For more information on Annovis Bio, please visit the Company's website www.annovisbio.com and follow us on LinkedIn and Twitter.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements relate to all information other than historical matters, such as expectations or forecasts of future events. Forward-looking statements may be identified by the use of words such as "forecast," "intend," "seek," "target," "anticipate," "believe," "expect," "estimate," "plan," "outlook," and "project" and other similar expressions that predict or indicate future events or trends or that are not statements of historical matters. Forward-looking statements with respect to the operations, strategies, prospects and other aspects of the business of Annovis Bio are based on current expectations that are subject to known and unknown risks and uncertainties, which could cause actual results or outcomes to differ materially from expectations expressed or implied by such forward-looking statements. These risks and uncertainties include but are not limited to delays in clinical trials and in reporting of the data. These and other risks and uncertainties are described more fully in the section titled "Risk Factors" in Annovis Bio's Annual Report on Form 10-K for the year ended December 31, 2022, and other periodic reports filed with the Securities and Exchange Commission. You are cautioned not to place undue reliance upon any forward-looking statements, which speak only as of the date made. Although it may voluntarily do so, from time to time, Annovis Bio undertakes no commitment to update or revise the forward-looking statements contained in this presentation, whether as a result of new information, future events or otherwise, except as required under applicable law.

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