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 30, 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 30, 2023, the Company issued a press release announcing the positive safety review by the Data and Safety Monitoring Board (DSMB) for its phase 2/3 trial of buntanetap, a drug candidate for moderate to mild Alzheimer's Disease patients. 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 30, 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 30, 2023

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

Exhibit 99.1

ANNOVIS BIO RECEIVES POSITIVE RECOMMENDATION TO CONTINUE PHASE 2/3 TRIAL OF BUNTANETAP FOR ALZHEIMER'S DISEASE PATIENTS FROM THE INDEPENDENT DATA AND SAFETY MONITORING BOARD (DSMB)

BERWYN, PENNSYLVANIA -- October 30, 2023 (BUSINESS WIRE)-- Annovis Bio, Inc. (NYSE: ANVS) ("Annovis"), announces the positive safety review by the Data and Safety Monitoring Board (DSMB) for its phase 2/3 trial of buntanetap, a drug candidate for moderate to mild Alzheimer's Disease (AD) patients. The DSMB recommended that Annovis continue the trial as originally designed.

The feedback from the DSMB was:

1. no drug-related SAEs (Serious Adverse Events)
2. each AE (Adverse Event): less than 5 percent
3. very low dropout rate: 4.7 percent

"The findings from the DSMB are yet another positive affirmation for the direction we are taking in our research", said Maria Maccecchini, Ph.D., CEO of Annovis. "We believe they are an important step along the way to potentially treating Alzheimer's Disease."

Annovis initiated the trial of buntanetap in late March 2023. The DSMB safety evaluation was set to occur when 90 patients completed 6 weeks of dosing. When the DSMB was convened on October 18, 2023, the data from a total of 107 patients was evaluated.

To date we have recruited a total of 281 patients out of the planned 320 patients; 76 patients have finished the study.

In our Alzheimer's Disease phase 2 trials, buntanetap was observed to improve cognition and speed of thinking. It was easily administered as a single pill taken once daily and was generally well-tolerated.

About the Phase II/III Trial

This study is a phase 2/3, randomized, double-blind, placebo-controlled trial investigating the efficacy, safety, and tolerability of buntanetap for mild to moderate AD patients on top of their standard of care. Buntanetap (formerly known as Posiphen or ANVS401) attacks neurodegeneration by reducing multiple neurotoxic proteins, thereby improving synaptic transmission and axonal transport, which is the information highway of the nerve cell. Dysfunction of synaptic transmission and axonal transport has been shown to be the cause of nerve cell degeneration and ultimately death. Unlike other AD drugs in development which attempt to remove only one toxic protein, buntanetap inhibits several toxic proteins before they can form, thereby preventing the formation of all the major neurotoxic proteins responsible for PD and AD.

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About Annovis Bio, Inc.

Headquartered in Berwyn, Pa., 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 information about the company's clinical trials and patents, visit anovisbio.com, and follow the company 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 safety or 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:

Maria Maccecchini