

**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): July 16, 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 July 16, 2024, Annovis Bio, Inc. (“The Company”) issued a press release announcing FDA approval to transition to its new crystal form of Buntanetap for future clinical trials. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

The following exhibits are being furnished herewith:

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release Dated July 16, 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: July 16, 2024

By: /s/ Maria Maccellini

Name: Maria Maccellini

Title: President and Chief Executive Officer

Annovis Bio Receives FDA Approval to Transition to New Crystal Form of Buntanetap

MALVERN, Pa., July 16, 2024 (GLOBE NEWSWIRE) -- via IBN – Annovis Bio Inc. (NYSE: ANVS) (“Annovis” or the “Company”), a late-stage clinical drug platform company pioneering transformative therapies for neurodegenerative disorders such as Alzheimer’s Disease (AD) and Parkinson’s Disease (PD), announced today that it has received approval from the U.S. Food and Drug Administration (FDA) to transition to a new solid form of buntanetap in future clinical trials.

In June 2024, Annovis announced the filing of a composition of matter patent for the new crystal form of buntanetap and a provisional patent for the manufacturing process of this new form. The Company conducted comprehensive bridge studies in various solvents and in animals, comparing the old semi-crystalline form with the new crystalline form of buntanetap. Additionally, Annovis developed an innovative large-scale manufacturing process for the new form. This comprehensive data was submitted to the FDA for review.

The FDA has now approved the continuation of buntanetap's development using the new crystal form. This positive response allows Annovis to conduct a comparative study between the old and new forms of buntanetap in a small, single-dose, bioavailability study in humans as part of the transition process.

About Buntanetap

Buntanetap (formerly known as Posiphen or ANVS401) targets neurodegeneration by inhibiting the formation of multiple neurotoxic proteins, including amyloid beta, tau, alpha-synuclein, and TDP43. This improves synaptic transmission, axonal transport, and reduces neuroinflammation. Dysregulation of these pathways has been shown to cause nerve cell degeneration and ultimately nerve cell death. By targeting these pathways, buntanetap has the potential to reverse neurodegeneration in Alzheimer’s, Parkinson’s, and other neurodegenerative diseases, thereby aiming to restore brain function and improve the quality of life for patients.

About Annovis Bio, Inc.

Headquartered in Malvern, Pennsylvania, Annovis Bio Inc. is dedicated to addressing neurodegeneration in diseases such as AD and PD. The company’s innovative approach targets multiple neurotoxic proteins, aiming to restore brain function and improve the quality of life for patients. For more information, visit www.annovisbio.com and follow us on [LinkedIn](#), [YouTube](#), and [X](#).

Investor Alerts

Interested investors and shareholders are encouraged to sign up for press releases and industry updates by registering for Email Alerts at <https://www.annovisbio.com/email-alerts>.

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. These statements include, but are not limited to, the Company's plans related to clinical trials. Forward-looking statements are based on current expectations and assumptions and are subject to risks and uncertainties that could cause actual results to differ materially from those projected. Such risks and uncertainties include, but are not limited to, those related to 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. Additional risk factors are detailed in the Company's periodic filings with the SEC, including those listed in the "Risk Factors" section of the Company's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q. All forward-looking statements in this press release are based on information available to the Company as of the date of this release. The Company expressly disclaims any obligation to update or revise its forward-looking statements, whether as a result of new information, future events, or otherwise, except as required by law.

Contacts

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