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): August 15, 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 2.02 Results of Operations and Financial Condition

On August 15, 2024, Annovis Bio, Inc. issued a press release announcing its financial results for the quarter ended June 30, 2024 and providing a corporate update. A copy of the press release is furnished herewith as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

The following exhibits are being furnished herewith:

(d) Exhibits

Exhibit No.	Description
99.1	Press Release Dated August 15, 2024
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: August 15, 2024

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

Exhibit 99.1

Annovis Bio Reports Second Quarter Financial Results and Provides Business Update

MALVERN, Pa., August 15, 2024 (GLOBE NEWSWIRE) -- via IBN – Annovis Bio Inc. (NYSE: ANVS) ("Annovis" or the "Company"), a clinical-stage drug platform company developing novel therapies for neurodegenerative diseases such as Alzheimer's disease (AD) and Parkinson's disease (PD), today announced financial results for the second quarter ended June 30, 2024, and provided a business update.

"The recent months have been productive for our company," said Maria Maccecchini, Ph.D., Founder, President, and CEO of Annovis Bio. "We've completed pivotal Phase 2/3 Alzheimer's and Phase 3 Parkinson's studies, both of which revealed very encouraging data for buntanetap. Additionally, we've introduced a new crystalline form of buntanetap with improved properties, further strengthening our IP portfolio. These milestones position us strongly as we move closer to providing much-needed treatments to patients."

Clinical Trial Updates

Alzheimer's Disease (AD)

- On April 29, 2024, Annovis Bio reported data from its completed Phase 2/3 AD study. The results showed that buntanetap significantly improved cognition in patients with early AD, with a 3.3-point improvement on the ADAS-Cog11 test after three months of treatment, compared to a 0.3-point improvement in the placebo group.
- The study also indicated a trend toward reduced plasma tau protein levels, consistent with previous findings, suggesting a potential disease-modifying effect of buntanetap.
- A follow-up analysis, on June 11, 2024, demonstrated that buntanetap was particularly effective in improving cognition among high-risk APOE4 carriers, showing a 3.15-point improvement.
- Buntanetap was found to be equally safe in both APOE4 carriers and non-carriers, with no instances of Amyloid-Related Imaging Abnormalities (ARIA) observed.

Parkinson's Disease (PD)

- On July 2, 2024, Annovis Bio announced the Phase 3 PD study data, which revealed that buntanetap led to significant improvements in both the Unified Parkinson's Disease Rating Scale (MDS-UPDRS) and cognition across several PD subpopulations.
- Buntanetap showed a particularly strong response in individuals diagnosed with PD for more than three years as well as in those with postural instability and gait disorder (PIGD).
- Moreover, buntanetap halted cognitive decline in all enrolled patients and improved cognition in those with mild dementia, mirroring the positive results observed in our AD studies.

Second Quarter 2024 Financial Results

- Annovis Bio received $7.1 million net cash from exercises of Canaccord warrants in July 2024.
- Cumulatively to date, received $7.0 million net cash from ELOC facility announced in April 2024.
- The Company's cash and cash equivalents totaled $4.0 million as of June 30, 2024, compared to $5.7 million as of December 31, 2023. The Company had 11.7 million shares of common stock outstanding as of June 30, 2024.
- After recent warrant exercises and ELOC share placements, as of August 14, 2024, Annovis had cash and cash equivalents of $12.1 million, which we believe is sufficient to support operations through the planned AD and PD FDA meetings in Fall and continuing until the initiation of the two pivotal studies planned.
- Total operating expenses for the three months ended June 30, 2024, were $7.8 million, which included research and development expenses of $5.8 million and general and administrative expenses of $2.0 million. This compares to total operating expenses for the three months ended June 30, 2023, of $9.8 million, which included research and development expenses of $8.2 million and general and administrative expenses of $1.5 million.
- Annovis Bio reported a $0.44 basic and diluted net loss per common share for the three months ended June 30, 2024. This compares to a $1.07 basic and diluted net loss per common share for the three months ended June 30, 2023.

Patents

- The Company filed a new composition of matter patent covering a novel crystal form of buntanetap and its use for treating and/or preventing various neurodegenerative conditions. The new crystalline form offers significant advantages over the less structured, old semi-crystalline form, including better solubility and stability as well as an additional 20 years of patent life
- The Company has filed a provisional patent for the methods of manufacturing this new crystalline form, covering the entire synthesis process—from basic starting materials to finished GMP product—suitable for large-scale manufacturing at ton quantities.
- On July 16, 2024, Annovis Bio received FDA approval to continue the phase 3 development with the new crystal form.
- Additionally, the Company was granted a U.S. patent for the use of buntanetap in the treatment of acute traumatic brain injury.

Team Updates

- On July 9, 2024, Annovis Bio announced the expansion of its team with several key appointments: Mark White as Chief Business Officer, Alexander Morin as Director of Strategic Communications, Hilda Maibach as Senior Vice President of Statistics, and Blake Jensen as Head of Quality.

Other Achievements

- On May 21, 2024, the Company shared a new scientific article focused on the similarities and differences in buntanetap's pharmacokinetic behavior between several animal models and humans, summarizing years of research.

- On August 6, 2024, Annovis Bio revealed new preclinical data showing a synergistic improvement on cognition when combining buntanetap with the GLP-1 agonist Trulicity®.

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.

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