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 13, 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 May 13, 2024, Annovis Bio, Inc. issued a press release announcing its financial results for the quarter ended March 31, 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 May 13, 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: May 13, 2024

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

Exhibit 99.1

Annovis Bio Provides Corporate Updates and Announces First Quarter 2024 Financial Results

MALVERN, Pa. -- **May 13, 2024** -- Annovis Bio, Inc. (NYSE: ANVS) ("Annovis" or the "Company"), a clinical-stage drug platform company developing novel therapies for neurodegenerative diseases, provided updates from across the organization and announced first quarter financial results.

Clinical Updates

AD Phase II/III Study

- On April 29, Annovis announced statistically significant Phase II/III data in patients with early Alzheimer's disease (AD).
    - Significantly higher rate of improvement in ADAS-Cog 11 scores in each treatment dose relative to placebo for patients with mild AD;
    - Improvement in cognition measured by ADAS-Cog 11 at three months was 3.3 points as compared to 0.3 for placebo, consistent with previous Phase II AD/PD and Discovery studies;
    - Plasma Tau protein levels were reduced, consistent with previous Phase II biomarker data.
- Based on the findings of this short study, Annovis plans to conduct a pivotal 18-month disease-modifying Phase III trial in biomarker-positive early AD patients.

PD Phase III Study

- On January 24, Annovis refined the timeline for Parkinson's disease (PD) Phase III data announcement, originally set for the end of January, due to necessary cleaning efforts required to deliver reliable and accurate results.
- On May 9, Annovis announced unblinding of the Phase III data and intends to release topline results in June of 2024.
- The Phase III trial was a randomized, double-blind, placebo-controlled trial investigating the efficacy, safety, and tolerability of buntanetap for early PD patients, on top of their existing standard of care. Patients were treated with 10 mg, 20 mg, or placebo for 6 months. Out of 616 patients screened, 523 were randomized and 471 completed the study across 67 sites (43 in the United States and 24 in the European Union).

Patents

- Annovis announced on January 30, 2024 the filing of a patent application covering the use of buntanetap and its analogues for the treatment of neuropsychiatric indications.
- This patent follows the U.S. Provisional Application No. 63/440,890, which was filed on January 24, 2023.
- This patent application addresses mental illnesses such as autism, attention deficit-hyperactivity disorder, bipolar disorder, major depressive disorder, anxiety and schizophrenia, which have been shown to share similar pathological abnormalities with certain neurodegenerative diseases, including disruptions in synthesis of neurotoxic proteins, impairment of axonal transport, inflammation, and nerve cell death.

First Quarter 2024 Financial Results

- The Company's cash and cash equivalents totaled $3.1 million as of March 31, 2024, compared to $5.8 million as of December 31, 2023. The Company estimates that active management of its cash and working capital positions, combined with the $0.8 million cash received in connection with its previously announced ELOC Purchase Agreement, will fund its operations into the fourth quarter of 2024. The Company had 11.0 million shares of common stock outstanding as of March 31, 2024.
- Total operating expenses for the three months ended March 31, 2024 were $7.8 million, which included research and development expenses of $6.5 million and general and administrative expenses of $1.3 million. This compares to total operating expenses for the three months ended March 31, 2023 of $10.0 million, which included research and development expenses of $7.8 million and general and administrative expenses of $2.2 million.
- Other income for the three months ended March 31, 2024 was $6.7 million, which included a $6.7 million non-cash gain from change in fair value of liability-classified warrants. This compares to other income for the three months ended March 31, 2023 of $0.2 million, which included $0.2 million of interest income.
- Annovis reported basic net loss per common share of $0.10 and diluted net loss per common share of $0.72 for the three months ended March 31, 2024. This compares to a basic net loss per common share of $1.19 and diluted net loss of $1.19 for the three months ended March 31, 2023.

Conferences

- Annovis participated in the International Conference on Alzheimer's and Parkinson's Diseases (AD/PD™ 2024), which took place in Lisbon, Portugal from March 5-9, 2024.

- On March 7, Maria Maccecchini participated in a forum discussion titled “New Insights in the Development of Biomarkers, Imaging, and Therapy of Alpha-Synuclein, LRKK2, and GBA Pathologies”.

Message from Dr. Maria Maccecchini

“The first quarter proved to be pivotal for our company as we continued to wind down our two recent clinical trials - Phase III in Parkinson’s and Phase II/III in Alzheimer’s. For our PD study, which concluded late last year, diligent efforts are underway to meticulously prepare the data, with expected delivery of topline results in June of this year. For the AD study, we successfully cleaned the data and were proud to announce cognitive improvements as measured by ADAS-Cog 11 in patients with early AD, showing us a pathway for continued clinical development of buntanetap. We extend our heartfelt gratitude to the patients and their families whose contribution was the driving force of our research aimed to bring new treatments to the market.”

- *Maria L. Maccecchini, Ph.D., Annovis Founder, President, and CEO*

About Buntanetap

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 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.

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.

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