

**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 4, 2022

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.)**

**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 2.02 Results of Operations and Financial Condition.

On May 4, 2022, Annovis Bio, Inc. issued a press release announcing its financial results for the quarter ended March 31, 2022 and providing a corporate update. A copy of the press release is furnished herewith as Exhibit 99.1.

The information furnished in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, and shall not be incorporated by reference in any filing under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release, dated May 4, 2022.
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 4, 2022

By: /s/ Jeffrey McGroarty
Name: Jeffrey McGroarty
Title: Chief Financial Officer



Annovis Bio Announces First Quarter 2022 Results and Provides Corporate Update

Berwyn, Pennsylvania – May 4, 2022 – Annovis Bio, Inc. (NYSE: ANVS) ("Annovis" or the "Company"), a clinical-stage drug platform company addressing neurodegenerative diseases, today announced first quarter financial results for the quarter ended March 31, 2022, and provided a corporate update.

Maria L. Maccicchini, Ph.D., Founder, President, and CEO of Annovis, commented, “we have made significant progress advancing buntanetap in Parkinson’s disease and Alzheimer’s disease this quarter. We received positive feedback from the U.S. Food and Drug Administration (FDA) for two Phase 3 clinical trials with buntanetap in early and late Parkinson’s disease. As our clinical trials advance, we have continued to build out our diverse team of highly motivated industry experts as we move to the next stage of clinical development.”

Recent Highlights and New Developments

- **Clinical Advancement of buntanetap for PD:** The Company held a successful Type B meeting with the FDA with regard to the Company's planned Phase 3 clinical studies of buntanetap for the treatment of Parkinson's Disease (PD). The FDA provided feedback on the initiation of the Phase 3 clinical studies of buntanetap for PD in parallel with the Alzheimer’s disease (AD) program. The agency detailed guidance on the specific endpoints, entry criteria, and further study parameters for two Phase 3 studies that would support a broad indication for both early and late PD.
 - **Announced Phase 3 Trial Design for PD:** The Company announced the trial design of the upcoming Phase 3 trial evaluating buntanetap in early PD. The study is designed to enroll 450 PD patients with Hoehn & Yahr scale scores of 1, 2 and 3 and randomize them at 1:1:1 ratio into placebo, 10mg or 20mg buntanetap once daily on top of their standard of care for six months. Movement Disorder Society-Sponsored Revision of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Part II and III will be used as primary endpoints, while total MDS-UPDRS and Participant Global Impression of Change will be secondary endpoints. In addition, Wechsler Adult Intelligence Scale, plasma biomarkers and Mini-Mental State Examination will be evaluated as exploratory endpoints.
 - **Expansion of the leadership team:** The Company announced the appointment of Eve Damiano, MS, RAC, as Senior Vice President of Regulatory Operations to advance the Company’s regulatory objectives. Eve joins Annovis with more than 35 years of experience in the biotechnology sector with a focus on the definition and execution of regulatory strategies. Additionally, the Company announced the promotion of Cheng Fang, Ph.D., to Senior Vice President of Research & Development to advance the Company’s clinical objectives. Cheng is an experienced neuroscientist with over a decade of experience studying neurodegenerative diseases.
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- **Receipt of USAN Assigned Name:** The Company announced receipt of the United States Adopted Names Council assigned name "buntanetap" for the Company's lead drug candidate previously known as ANVS401/Posiphen.

Financial Results for the First quarter of 2022

Cash, cash equivalents, and marketable securities were \$42.7 million as of March 31, 2022. Research and development expenses for the quarter ended March 31, 2022, were \$2.8 million, compared to \$2.4 million for the same period in 2021. The increase was primarily the result of an increase of \$1.2 million in stock-based compensation expense, partially offset by a decrease of \$0.7 million in expenses related to the Company's two Phase 2a clinical trials which were completed in 2021. General and administrative expenses for the quarter ended March 31, 2022, were \$3.1 million, compared to \$0.8 million for the same period in 2021. The increase was primarily the result of increases of \$2.2 million in stock-based compensation expense and \$0.1 million in professional fees.

For the quarter ended March 31, 2022, Annovis reported a net loss of \$5.9 million, compared to a net loss of \$3.2 million for the same period in 2021.

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, including Alzheimer's in Down Syndrome (AD-DS). We believe that we are the only company developing a drug for AD, PD, and AD-DS 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

Statements in this press release contain "forward-looking statements" that are subject to substantial risks and uncertainties. Forward-looking statements contained in this press release may be identified by the use of words such as "anticipate," "expect," "believe," "will," "may," "should," "estimate," "project," "outlook," "forecast" or other similar words, and include, without limitation, statements regarding the timing, effectiveness, and anticipated results of buntanetap clinical trials. Forward-looking statements are based on Annovis Bio, Inc.'s current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate. These and other risks and uncertainties are described more fully in the section titled "Risk Factors" in the Annual Report on Form 10-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission. Forward-looking statements contained in this announcement are made as of this date, and Annovis Bio, Inc. undertakes no duty to update such information except as required under applicable law.

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