

**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): April 3, 2023

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 April 3, 2023, Annovis Bio, Inc. issued a press release announcing its financial results for the quarter and year ended December 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 April 3, 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: April 3, 2023

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

ANNOVIS BIO ANNOUNCES FOURTH QUARTER AND FULL YEAR 2022 FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

BERWYN, Penn., April 3, 2023 /PRNewswire/ -- Annovis Bio, Inc. (NYSE: ANVS) ("Annovis" or the "Company"), a clinical-stage drug platform company addressing neurodegenerative diseases, has announced fourth quarter and full year financial results for the period ended December 31, 2022, and reviewed recent accomplishments.

**Fourth Quarter Highlights and New Developments**

- **Received approval for European Union clinical trial sites for the Phase 3 study of buntanetap for the treatment of early Parkinson's disease:** On February 8, 2023, the Company announced the approval for additional European clinical trial sites for the ongoing Phase 3 study of buntanetap for the treatment of Parkinson's disease ("PD"). Annovis is actively recruiting for the ongoing Phase 3 study with approximately 53 clinical trial sites open and currently enrolling in the United States. The approval adds an additional approximately 49 sites in the EU for the Company's Phase 3 study of buntanetap for the treatment of Early PD.
 - **Announced filing of patent application covering the administration of buntanetap and its analogues for the treatment of mental illnesses:** On February 1, 2023, the Company announced the filing of a provisional patent application that extends the breadth of its platform from neurodegenerative to neuropsychiatric indications: "*Treatment of mental illness via administration of buntanetap and analogues.*"
 - **Announced new appointments to strengthen its senior leadership team:** On January 6, 2023, the Company announced the appointment Michael Christie, Ph.D. as Vice President of Process Chemistry and David Prohaska as Vice President of Toxicology and Pharmacology. Dr. Christie has over 40 years of experience in the pharmaceutical industry and formally served as the Senior Director of Chemical Process and R&D for Teva Pharmaceuticals. Mr. Prohaska brings 25 years of experience in all aspects of preclinical drug development and has a long track record of successful FDA submissions with multiple drug approvals. Mr. Prohaska joined Annovis from Aravive Biologics where he served as the Director of Preclinical Development and Clinical Operations Support.
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- **Publication of Phase 1/2 clinical data in *The Journal of Prevention of Alzheimer's Disease*:** On October 11, 2022, the Company announced the publication of a study, titled '*Buntanetap, a Novel Translational Inhibitor of Multiple Neurotoxic Proteins, Proves to Be Safe and Promising in Both Alzheimer's and Parkinson's Patients*', evaluated safety, pharmacokinetics, biomarkers, and efficacy of buntanetap in treating early AD and PD patients. Buntanetap was observed to be well tolerated and significantly improved cognition in AD patients and motor function in PD patients.
- **Receipt of FDA authorization to proceed with Phase 2/3 trial for buntanetap in mild to moderate Alzheimer's disease (AD):** On October 6, 2022, the Company announced that the FDA authorized the Phase 2/3 clinical study of buntanetap in mild to moderate AD. The Phase 2/3 study is a randomized, double-blind, placebo-controlled trial investigating the efficacy, safety, and tolerability of buntanetap in mild to moderate AD patients. The trial will enroll a total of 320 mild to moderate AD patients to be treated with 7.5, 15 or 30mg of buntanetap or placebo, in addition to any drugs they regularly take, for three months.
- **Interim analysis for Phase 3 study of buntanetap for the treatment of early Parkinson's disease (PD):** On March 31, 2023, the Company announced that it had received the results of the pre-planned blinded interim analysis conducted by a data analytics provider based on 132 patients from all cohorts collectively for which baseline and two-month data was available. As the interim analysis was conducted at two months of the six-month endpoint and only on 132 patients, it may not be indicative of the results at six months for the full patient population because as the trial progresses, clinical outcomes may materially change as patient enrollment continues and more patient data become available, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Based on the results of the interim analysis, the Company intends to proceed with the trial as planned in accordance with the previously established protocol.

Maria L. Maccicchini, Ph.D., Founder, President, and CEO of Annovis, commented: “The fourth quarter and subsequent announcements in early 2023 highlight continued execution and productivity across many facets of our business. We are pleased with the pace of enrollment in our ongoing clinical trials. We expect to report a blinded interim analysis of our Phase 2/3 Alzheimer’s study in Fall 2023. We are also building an expansive intellectual property estate surrounding the use of buntanetap and its analogues across a myriad of neuro-inflammatory diseases and conditions. As our clinical activities continue to expand, we are also managing this growth through the appointments of key senior-level professionals who will play a pivotal role as we reach key inflection points in our clinical programs. We believe 2023 promises to be an exciting year for Annovis driven by our team’s continued execution, and the strong therapeutic potential of our lead drug candidate, buntanetap, to address the unmet medical need in Alzheimer’s and Parkinson’s disease.”

Financial Results for the Fourth Quarter of 2022

Cash and cash equivalents were \$28.4 million as of December 31, 2022. Research and development expenses for the quarter ended December 31, 2022 were \$6.2 million, compared to \$2.9 million for the same period in 2021. The increase was primarily the result of an increase of \$4.3 million in clinical expenses, as the Company incurred costs related to its Phase 3 study in early PD patients and its Phase 2/3 Alzheimer's study, partially offset by a decrease of \$1.0 million in stock-based compensation expense. General and administrative expenses for the quarter ended December 31, 2022 were \$1.6 million, compared to \$3.0 million for the same period in 2021. The decrease was primarily the result of a decrease of \$1.5 million in stock-based compensation expense.

For the quarter ended December 31, 2022, Annovis reported a net loss of \$7.7 million, compared to a net loss of \$5.9 million for the same period in 2021.

Financial Results for the Full Year 2022

Research and development expenses for the year ended December 31, 2022, were \$16.5 million, compared to \$8.5 million for the same period in 2021. The increase was primarily the result of an increase of \$6.6 million in clinical expenses, as the Company incurred costs related to its Phase 3 study in early PD patients, its Phase 2/3 Alzheimer's study and an increase of \$1.4 million in stock-based compensation expense. General and administrative expenses for the year ended December 31, 2022 were \$9.0 million, compared to \$6.1 million for the same period in 2021. The increase was primarily the result of an increase of \$3.1 million in stock-based compensation expense.

For the full year ended 2022, Annovis reported a net loss of \$25.3 million, compared to a net loss of \$14.5 million in 2021.

About Buntanetap

Buntanetap (previously known as ANVS401 or Posiphen) is an oral translational inhibitor of neurotoxic aggregating proteins (TINAPs), which mode of action leads to a lower level of neurotoxic proteins and consequently less toxicity in the brain. In a Phase 1/2 clinical trial in Alzheimer's disease (AD) and Parkinson's disease (PD) patients, buntanetap was shown to be well-tolerated and its pharmacokinetics were found to be in line with levels measured earlier in humans, meeting both the primary and secondary endpoints. Additionally, exploratory endpoints were also met, as treatment with buntanetap resulted in statistically significant improvement in motor function in PD patients and cognition in AD patients. Presently buntanetap is being studied in a Phase 3 study in early PD patients and in a Phase 2/3 study in mild to moderate AD patients.

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. We believe that we are the only company developing a drug for AD and PD that is designed to inhibit more than one neurotoxic protein, and has a mechanism of action designed to restore nerve cell axonal and synaptic activity. By improving brain function, our goal is to treat memory loss and dementia associated with AD as well as body and brain function associated with PD. Annovis conducted two Phase 1/2 studies: one in AD patients and one in both AD and PD patients. In the AD/PD study buntanetap showed improvements in cognition in AD as well as body and 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

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.
