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 2, 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 April 2, 2024, Annovis Bio, Inc. issued a press release announcing its financial results for the fourth quarter and the fiscal year ended December 31, 2023 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.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release Dated April 2, 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: April 2, 2024

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

Exhibit 99.1

ANNOVIS BIO PROVIDES CORPORATE UPDATES AND REPORTS FOURTH QUARTER AND FULL YEAR 2023 FINANCIAL RESULTS

Tue, 02 Apr 2024

MALVERN, Pa., April 02, 2024 (GLOBE NEWSWIRE) -- Annovis Bio, Inc. (NYSE: ANVS) (“Annovis” or the “Company”), a clinical-stage drug platform company developing novel therapies for neurodegenerative diseases, today provided a summary of corporate updates and reported fourth quarter and full year 2023 financial results.

Fourth Quarter 2023 Highlights

Clinical Updates

Announced Last Patient Last Visit in the Phase III Study of Buntanetap in Parkinson’s Disease (PD)

On December 5, 2023, the Company announced the last patient last visit for its PD Phase III study of buntanetap and reported a substantial level of participation with patients enrolled at record pace. Out of 616 total patients screened, 523 were enrolled and 471 completed the trial across 67 sites (43 in the United States and 24 in the European Union). The Company confirmed screen failure (15%) and drop out (9.9%) rates that were below projections.

Reported Full Enrollment for its Phase II/III Alzheimer’s Disease (AD) Trial Exceeding Original Projections

On November 27, 2023, the Company announced full enrollment for its AD Phase II/III study of buntanetap. With over 700 patients screened, a total of 353 patients were enrolled across 54 sites in the United States, well above originally planned 320 patients, exceeding the initial projections. The Phase II/III study was a randomized, double-blind, placebo-controlled trial investigating the efficacy, safety, and tolerability of buntanetap in patients with mild to moderate AD. Patients received either one of three doses of buntanetap (7.5mg, 15mg, or 30mg) or placebo on top of their standard of care for 12 weeks. The Company recently declared a database lock and updated the timeline for top line efficacy data, now expected in April.

Issued Novel Biomarker Measurements in Plasma of Parkinson's Patients

On November 2, 2023, the Company reported new data of important biomarkers in plasma of PD patients, in addition to previously measured biomarkers in CSF. The data showed a statistically significant drop in the levels of TAR DNA-binding protein 43 (TDP43), one of the neurotoxic proteins which is correlated with impaired axonal transport, inflammation, and nerve cell death. To our knowledge, it is the first time that a drug has reduced TDP43 levels in humans. The data also supports the unique mechanism of action of buntanetap in that it inhibits more than one neurotoxic aggregating protein. Evaluating biomarkers in plasma rather than in CSF is a considerable improvement for patients as well as for the sites conducting the study. Plasma biomarkers allow for monitoring the progression of the disease, while making it easy on both patients and doctors.

Appointments

Appointed Andrew Walsh as Vice President Finance

On December 1, 2023, the Company appointed Andrew Walsh as VP Finance, whose 12 years of experience in finance operations proves crucial for the Company's continued success. Mr. Walsh joined Annovis from Ocugen, a clinical stage biotechnology company developing novel gene and cell therapies as well as vaccines, where he served as Senior Director, Finance and Treasury. Andrew began his career at KPMG in corporate tax and has since held roles of increasing responsibility at InVentiv Health, PQ Corporation and Potters Industries.

Conferences

Participated in the 139TH Yale CEO Summit

On December 11, 2023, Maria Maccecchini, Founder, President and CEO of Annovis, was selected to participate in the Yale CEO Summit, a bi-annual event which brings together influential CEOs from major US Fortune 500 companies for impactful collaborative dialogues themed around "Re-imagining Your Strategic Mission with Your Current Leadership."

Message from Dr. Maria L. Maccecchini

“During the fourth quarter of last year, we witnessed a remarkable momentum in our mission to bring novel therapeutics for neurodegenerative diseases, as both of our clinical trials for Alzheimer’s and Parkinson’s progressed significantly. In December, we completed the Phase III PD study, and we are currently in the process of meticulously cleaning the data. The AD Phase II/III study was completed in February, and we announced that we cleaned the data to our satisfaction and will release top-line efficacy results in April. As our drug development programs stride forward, we also appointed a key senior-level professional who will play a pivotal role in our financial operations. Annovis is poised for an exhilarating year ahead, driven by our unwavering team execution.”

Financial Results for the Fourth Quarter of 2023

As of December 31, 2023, Annovis had cash and cash equivalents of $5.8 million, compared to $28.4 million at December 31, 2022. The decrease in cash and cash equivalents was related to cash burn from funding of our operations, partially offset by our March 2023 ATM and November 2023 Equity Offering. For the quarter ended December 31, 2023, Annovis reported a net loss of $22.2 million, compared to a net loss of $7.7 million for the same period in 2022.

Research and development expenses for the quarter ended December 31, 2023 were $8.9 million, compared to $6.2 million for the same period in 2022. The increase was primarily the result of an increase of $3.2 million in clinical and CMC expenses, as the Company incurred substantial costs related to its Phase III PD study and its Phase II/III AD study. This increase was partially offset by a decrease of $0.5 million in stock-based compensation expense, driven by lower option fair values being amortized in 2023 as compared to 2022.

General and administrative expenses for the quarter ended December 31, 2023 were $1.5 million, compared to $1.6 million for the same period in 2022. The decrease was primarily the result of a decrease of $0.1 million in stock-based compensation expense, driven by lower option fair values being amortized in 2023 as compared to 2022.

Other income (expense) for the quarter ended December 31, 2023 was ($11.8) million, compared to $0.1 million for the same period in 2022. The decrease was primarily related to recording $11.8 million of expense related to change in fair value of warrants classified as liabilities.

Financial Results for the Full Year of 2023

For the full year ended 2023, Annovis reported a net loss of $56.2 million, compared to a net loss of $25.3 million in 2022.

Research and development expenses for the year ending December 31, 2023, were $38.8 million, compared to $16.5 million for the same period in 2022. The increase was primarily the result of an increase of $23.7 million in clinical and CMC expenses, as the Company incurred substantial costs related to its Phase III PD study as well as its Phase II/III AD study. This increase was partially offset by a decrease of $1.2 million in stock-based compensation expense driven by lower option fair values being amortized in 2023, as well as a decrease of $0.5 million for lower employee allocations to R&D.

General and administrative expenses for the year ended December 31, 2023 were $6.2 million, compared to $9.0 million for the same period in 2022. The decrease was primarily the result of a decrease of $3.4 million in stock-based compensation expense, driven by lower option fair values being amortized in 2023 as compared to 2022, partially offset by an increase of $0.9 million in professional fees incurred as a result of the material weakness identified in 2023 and associated remediation efforts.

Other income (expense) for the quarter ended December 31, 2023 was ($11.2) million, compared to $0.2 million for the same period in 2022. The decrease was primarily related to recording $11.8 million in change in fair value of warrants classified as liabilities, offset by $0.5 million in increased interest income, given higher average interest rates during 2023.

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 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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