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 11, 2021

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.)

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	NYSE American

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 7.01 Regulation FD Disclosure.

On August 11, 2021, Annovis Bio Inc. (the "Company") posted on its website at www.annovisbio.com under "Investors & Media" frequently asked questions related to recent interim results among both Alzheimer's disease (AD) and Parkinson's disease (PD) patients from Phase 2a clinical trials of the Company's lead compound, ANVS401. A copy of the frequently asked questions is furnished as Exhibit 99.1.

The information in this Item 7.01, Item 9.01 and Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liability of such section, nor shall it be deemed incorporated by reference in any filing of the Company under the Securities Act of 1933 or the Securities Exchange Act of 1934, regardless of any general incorporation language in such filing, unless expressly incorporated by specific reference in such filing.

Cautionary Statement Regarding Forward-Looking Information

This current report on Form 8-K contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than those of historical fact in the frequently asked questions documents are forward-looking statements. Forward-looking statements may be identified by terminology such as "believe," "anticipate," "plan," "may," "intend," "will," "should," "expect," "estimate," "potential" and "continue" and similar expressions, including the negative of these words, but not all forward-looking statements contain these words. Forward-looking statements include, but are not limited to, statements regarding the Company's expectations and timelines regarding the Company's Phase 2a clinical trial and expectations regarding current or future clinical trials. Forward-looking statements are based on the Company'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. Actual results could differ materially from those described or implied by such forward-looking statements as a result of various important factors, including, without limitation, the failure of preliminary data to predict final study results and impacts from the COVID-19 pandemic and the other important factors 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, 2020 filed with the Securities and Exchange Commission ("SEC") and elsewhere in our filings and reports with the SEC. Forward-looking statements speak as of the date they are made, and the Company undertakes no obligation to update them except as may be required under applicable law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Frequently Asked Questions - Annovis Bio Phase 2a Data Results (furnished herewith).
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 11, 2021

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

Exhibit 99.1

Frequently Asked Questions
Annovis Bio Phase 2a Data Results

1. What interim results from the Phase 2a study of ANVS401 were recently announced by Annovis Bio? Why did some people believe the company's recent interim data readout was negative?

Answer: On July 28, we announced interim results among both Alzheimer's disease (AD) and Parkinson's disease (PD) patients from Phase 2a clinical trials of our lead compound, ANVS401 (Posiphen).

The results were positive – over the first 25 days of treatment, the initial patient cohorts demonstrated statistically significant positive results in both cognitive and motor skills. The biomarkers presented and analyzed also corroborated the efficacy of ANVS401.

We are aware that some initial reporting after our presentation at the AAIC 2021 conference included an error in which the scores of the WAIS test were transposed between placebo and treated PD patients. We have received a number of questions regarding this error and believe it led some people to conclude that the placebo was more effective than treatment with ANVS401, which is incorrect.

2. Explain what is statistically significant in drug development?

Answer: Statistical significance separates random events from events that are caused by a specific intervention. The FDA looks at a drug as being effective if the efficacy measured has a less than 5% chance ($p<0.05$) of being due to the random daily behavior of patients. If the effect observed has a greater than 5% chance ($p>0.05$) of being due to random behavior, then it is called non statistically significant and it means that the drug did not affect treated patients.

In the case of ANVS401 we saw statistically significant changes ($p<0.05$) in ADAS-Cog11, MDS-UPDRS and WAIS, showing efficacy of the drug in AD and PD patents.

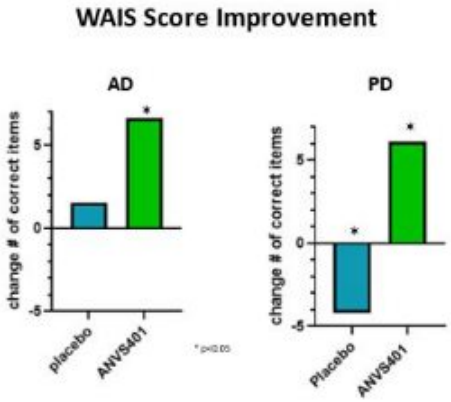
We also showed non statistically significant data in the mini mental state examination (MMSE) and clinical dementia rating sum of boxes (CDR), reflecting that the scores were due to random changes in behavior.

3. What does the WAIS Scale measure; and what did the scale reveal in the Phase 2a data?

Answer: The WAIS coding scale measures visual-motor dexterity, associative nonverbal learning, and nonverbal short-term memory. It measures fine-motor dexterity, speed, accuracy, and ability to manipulate a pencil and perceptual organization.

4. How did the Parkinson's disease patients score using the WAIS test?

Answer: After 25 days of treating PD patients with 80 mg a day of ANVS401, the speed and accuracy of the patients is faster than at baseline (6.1 points, $p<0.05$) and faster than the placebo treated group (9.8 points, $p<0.05$). Both scores are statistically significantly better in the treated group, whether compared to baseline or to placebo.



5. How did the Alzheimer's disease patients score using the WAIS test?

Answer: After 25 days of treating AD patients with 80 mg a day of ANVS401, the speed of the treated group is faster than at baseline, and the patients on average coded 6.6 more correct fields. The improvement in treated AD patients compared to baseline was statistically significant. At 25 days, the placebo group improved slightly, but not as much as the ANVS401 treated group.

6. Is the Phase 2a data from the WAIS statistically significant?

Answer: Yes, the outcome of the WAIS coding test is statistically significant and confirms the statistical significance of the ADAS-Cog11 and MDS-UPDRS tests in both AD and PD patients.

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7. How did the AD and PD patients fare on the MMSE, and CDR?

Answer: This study was planned with the primary endpoints being biomarkers. The fact that we saw cognitive and functional improvement is an additional benefit.

We saw statistically significant improvements in the ADAS-Cog11, MDS-UPDRS, and in the WAIS tests and not statistically significant results in the MMSE and CDR.

While we conducted all of these tests to look at a full cognition panel, we did not necessarily expect the MMSE and CDR to change, because while the ADAS-Cog11 and MDS-UPDRS are nimble tests that can show a change in a short period of time, the MMSE and CDR are less sensitive and generally would not be expected to change in one month.

8. Did the placebo outperform ANVS401 in the MMSE and CDR tests?

Answer: No, the changes in patients in the MMSE and CDR tests were not statistically significant, which is interpreted to mean that the difference is due to randomness and not to the effect of the drug, whereas statistical significance means that the change is due to the effect of the drug.

9. Why is Annovis Bio's Phase 2a cytotoxic cascade data important?

Answer: The cytotoxic cascade data is important because chronic brain insults lead to high levels of neurotoxic proteins, that cause impairment in the axonal transport, inflammation, and nerve cell death, and ultimately impair a patient's cognition and/or movement.

10. Did the Phase 2a data reveal ANVS401 lowered levels of neurotoxic proteins in AD and PD patients?

Answer: Yes, the Phase 2a data revealed ANVS401 lowered levels of neurotoxic proteins for both AD and PD patients and improved cognition and motor function. The data also revealed significant reductions of neurotoxic proteins levels and inflammation, as well as biomarkers for axonal damage, and highlighted the efficacy data. Our data reveals ANVS401 improves axonal transport in vitro and in vivo, and by doing so restores normal brain function.

11. What is the take-home message of the first 28 patients treated with ANVS401?

Answer: ANVS401 showed that it improved cognition in Alzheimer's disease, as measured by ADAS-Cog11 and WAIS assessment scales. ANVS401 improved movement in Parkinson's disease patients as measured by MDS-UPDRS and WAIS. The efficacy data is corroborated by the biomarkers of the toxic cascade that all point in the direction of an improvement in AD and PD.

This is the first double-blind placebo-controlled study ever conducted of which we are aware that shows cognitive improvement in AD and functional improvement in PD patients by the same therapy.

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