# 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): October 5, 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 October 5, 2021, Annovis Bio Inc. (the "Company") issued a press release announcing results from the completed dose response Phase 2 clinical trial of ANVS401. A copy of the Press Release is attached to this Current Report on Form 8-K as Exhibit 99.1.

On October 5, 2021, at 9:00 am ET the Company will host an investor conference call to discuss the results of the completed dose response Phase 2 clinical trial of ANVS401. Interested parties can participate through the following link: https://russopr.zoom.us/j/87423723968. A copy of a presentation to be referenced during the investor conference call is furnished as Exhibit 99.2.

The information in this Item 7.01, Item 9.01, Exhibit 99.1 and Exhibit 99.2 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, including that clinical trials may be delayed; that the data reported herein is only from a Phase 2a study and subsequent clinical trials must be conducted; and that any anticipated meeting with or presentation to the FDA may be delayed. 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 | Press Release, dated October 5, 2021 (furnished herewith). |
| 99.2 | Presentation – New Parkinson's Efficacy Data, dated October 5, 2021 (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: October 5, 2021

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

**Exhibit 99.1**

**Annovis Bio Announces Positive Phase 2 Efficacy Data for the Treatment of Parkinson's Disease**

*Data Shows Statistically Significant Improvements in Speed and Motor Function in PD Patients*

*Annovis Bio to Request Meeting with FDA on Next Steps in Clinical Development*

*Investor Conference Call to be Hosted Tuesday, October 5th, 2021, at 9:00 am ET*

**BERWYN, PA., October 5, 2021 --** Annovis Bio, Inc. (NYSE American: ANVS) ("Annovis" or the "Company"), a clinical-stage drug platform company addressing Alzheimer's disease (AD), Parkinson's disease (PD) and other neurodegenerative diseases, today announced results from the completed dose response Phase 2 clinical trial of ANVS401 in 54 PD patients, which found that once-daily ANVS401 was superior to placebo in improving motor function.

The second part of the study expanded on the original 14 AD and 14 PD patients by recruiting an additional 40 PD patients for a total of 54 PD patients, who were treated with either 0mg, 5mg, 10mg, 20mg, 40mg or 80mg of ANVS401 once daily. Safety and two psychometric assessments - the coding test of the Wechsler Adult Intelligence Scale (WAIS) and the MDS-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) - were conducted at day 0 and day 25, comparing ANVS401-dosed PD patients with those dosed with placebo. ANVS401 has been found to be well-tolerated and safe with no adverse effects related to treatment observed.

When compared to the placebo group, statistically significant improvements in WAIS coding scores were observed in PD patients taking ANVS401 5mg, 20mg and 80mg once daily, highlighting increased motor-dexterity, as well as speed and accuracy compared to placebo (Figure 1). Further, PD patients taking ANVS401 5mg, 20mg and 80mg also achieved statistically significant improvements from baseline in the same test (Figure 1). PD patients treated with ANVS401 10mg and 20mg once daily showed statistically significant improvements in the UPDRS 2, 3, 4, and in total MDS-UPDRS test compared to baseline (Figure 2).

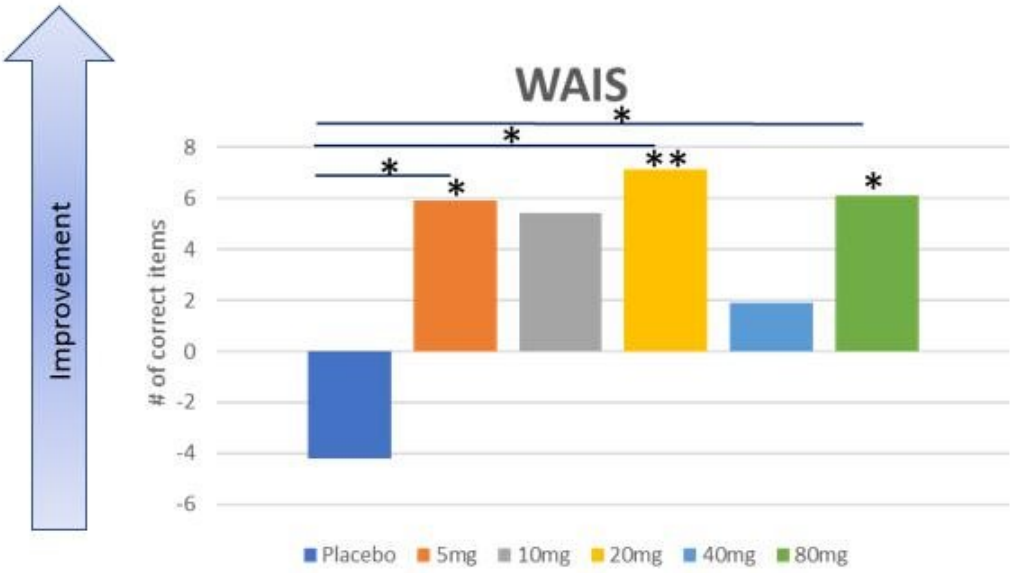


Figure 1 – WAIS Coding Test Results for 54 PD Patients – Statistical significance from baseline is signified by an asterisk on the top of a dose bar; statistical significance from placebo is signified by an asterisk on a line from the placebo to a dose bar. Single asterisks represent $p<0.05$, while two asterisks represent $p<0.01$.

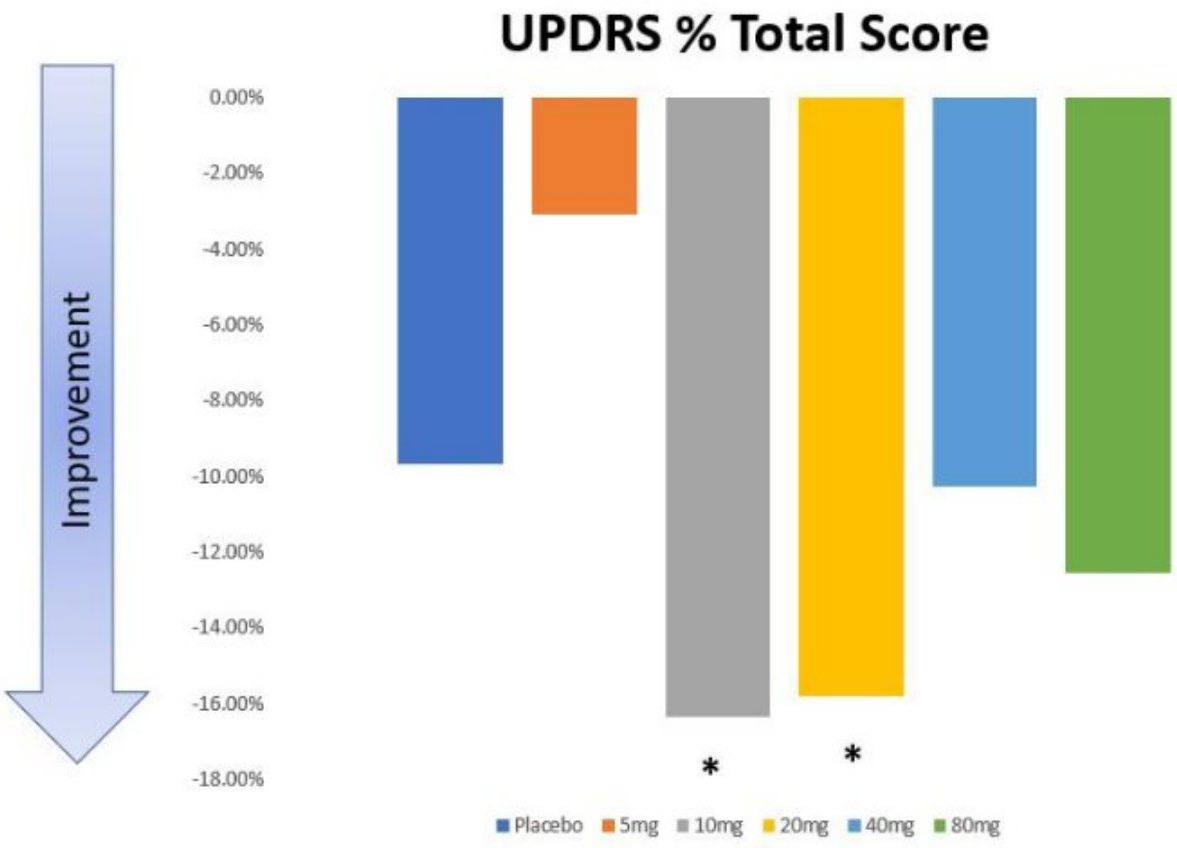


Figure 2 – MDS-UPDRS Total Results for 54 PD Patients – Patients dosed with 10mg and 20mg showed marked improvement when compared to baseline for motor control and function. Statistical significance from baseline is signified by an asterisk on the bottom of a dose bar. Single asterisks represent $p<0.05$.

This dosing study shows that ANVS401 is efficacious across the tested dose range when measured by WAIS coding and shows better efficacy around 10 to 20mg once per day when measured by MDS-UPDRS. This dose range provides guidance as to what doses to use in the upcoming phase 3 studies in AD and PD patients.

"We are thrilled by these improvements in motor function of PD patients. Through examination of this dose-response, we can determine an optimal safe and efficacious dose as we move forward towards initiation of Phase 3 clinical trials with much larger patient populations and longer timelines. These positive efficacy results, which expand on our previous data from AD and PD patients, add clarity to the benefits that ANVS401 may offer to patients suffering from these chronic neurodegenerative diseases," said Founder, President and CEO of Annovis, Maria L. Maccecchini, Ph.D. "We are still analyzing certain biomarker data from the 54 PD patients and will share the results when they are available. We will be asking the FDA for a meeting to receive guidance on next steps in clinical development in light of the AD/PD Phase 2 clinical results."

Annovis Bio will host an investor conference call today, October 5th, 2021, at 9:00 am ET. Interested parties can participate through the following link: https://russopr.zoom.us/j/87423723968

**About WAIS and MDS-UPDRS Psychometric Assessments**

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

The MDS-UPDRS evaluates several motor and non-motor experiences specific to the progression of Parkinson's disease, including cognitive impairment, general mental state, facial expression, tremors, and other key features. The UPDRS is the current standard for clinical examination of patients diagnosed with PD.

**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 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. We have two ongoing Phase 2 studies: one in AD patients and one in both AD and PD patients. In the AD/ PD study our drug improves memory loss and dementia associated with AD, as well as body and brain function in PD.

For more information on Annovis Bio, please visit the company's website: www.annovisbio.com

**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 using 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 ANVS401 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, including that clinical trials may be delayed; that the data reported herein is from a Phase 2a study and subsequent clinical trials must be conducted; and that any anticipated meeting with or presentation to the FDA may be delayed. 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, 2020, 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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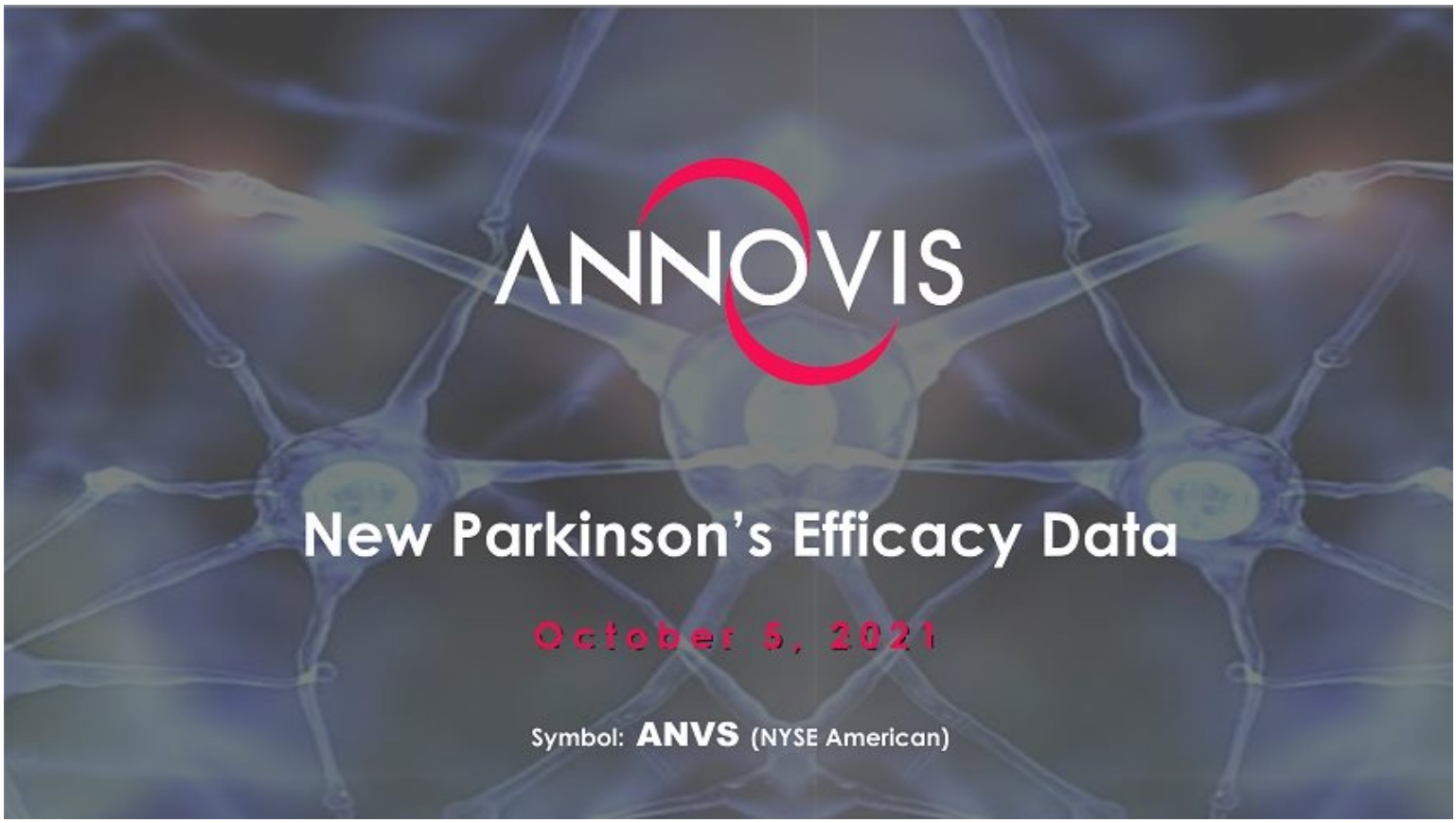
**Investor and Media Contact:**
Nic Johnson
Russo Partners, LLC
(303) 482-6405
nic.johnson@russopartnersllc.com

**Exhibit 99.2**


ANNOVIS
New Parkinson's Efficacy Data
October 5, 2021
Symbol: ANVS (NYSE American)

## FORWARD-LOOKING STATEMENTS

Statements in this presentation contain "forward-looking statements" that are subject to substantial risks and uncertainties. Forward-looking statements contained in this presentation 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 Annovis Bio, Inc.'s expectations regarding projected timelines of clinical trials, and expectations regarding current or future 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, including that clinical trials may be delayed; that the data reported herein is only from a Phase 2a study and subsequent clinical trials must be conducted; and that any anticipated meeting with or presentation to the FDA may be delayed. 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, 2020 and other reports filed with the Securities and Exchange Commission. Forward-looking statements contained in this presentation are made as of this date, and Annovis Bio, Inc. undertakes no duty to update such information except as required under applicable law.


# CORPORATE UPDATES

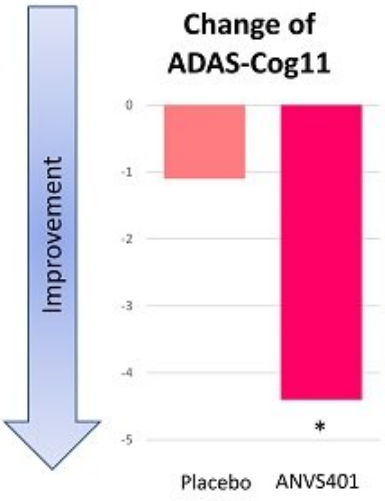
| | |
|---|---|
| **Quarterly Calls** | • Starting next year, we will conduct quarterly conference calls |
| **Appointments** | • We are actively in the process of hiring a Chief Medical Officer |
| **PD Data** | • General overview of new positive Parkinson's disease top-line efficacy data |


# TWO PHASE 2 CLINICAL TRIALS

| | AD Trial | PD Trial |
|---|---|---|
| Therapeutic Area | Early to Moderate AD and PD | |
| Phase | 2 | |
| Patients | 14 | 14 + 40 |
| Design | Double-Blind, Placebo-Controlled, Biomarker Study | |
| Endpoints | Reversal of Toxic Cascade | |
| Exploratory | Efficacy | |

# IMPROVED COGNITION IN AD PATIENTS – ADAS-Cog11

**Data from 14 AD patients**

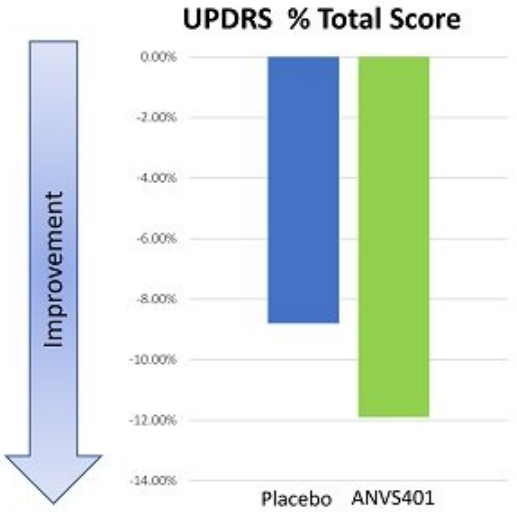



From baseline to 25 days in the ANVS401-treated group, ADAS-Cog11 improved by 4.4 points, a statistically significant improvement of 30%. Compared to placebo at 25 days the treated group is 3.3 points better than the placebo, an improvement of 22%.

In this presentation, statistical significance from baseline Is shown by an asterisk on the top or bottom of the dose bar. Statistical significance from placebo is shown by an asterisk on a line from the placebo to the dose bar; * $p<0.05$; ** $p<0.01$

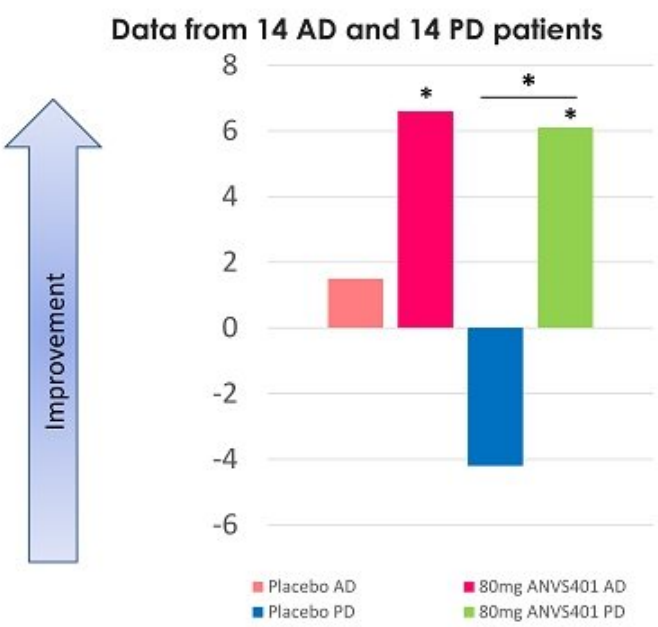
# EFFICACY TREND IN PD PATIENTS – MDS-UPDRS TEST

**Data from 14 PD patients - Total UPDRS**




ANVS401-treated group showed trends of improvement in UPDRS test total score compared to placebo

# IMPROVED SPEED AND ACCURACY IN AD AND PD PATIENTS
## WAIS CODING TEST




The WAIS coding test measures speed in movement and thinking. Treated AD patients show a statistically-significant 23% improvement from baseline. Treated PD patients show a statistically-significant 30.5% improvement compared with placebo, and a statistically-significant improvement from baseline.

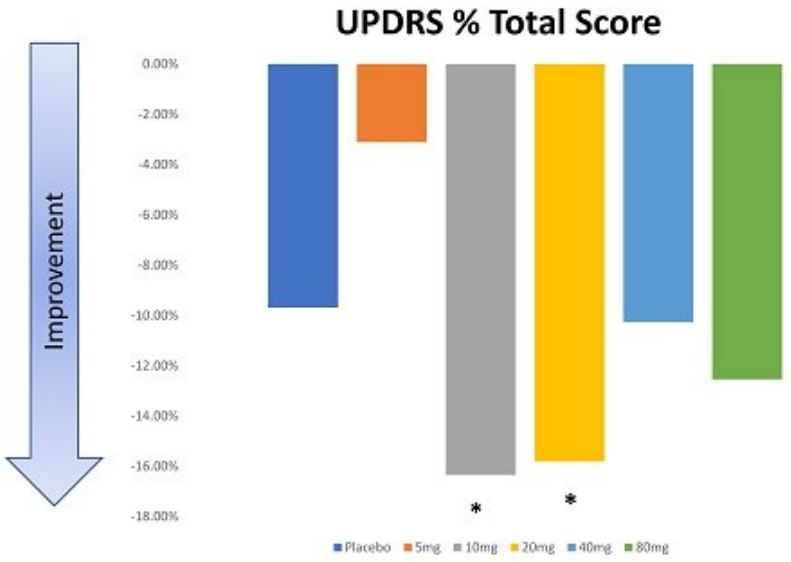

## COMPLETE 54 PD PATIENT CLINICAL TRIAL

| PD | |
|---|---|
| Therapeutic Area | Early to Moderate PD |
| Phase | 2 |
| Patients | 54 |
| Design | Double-Blind, Placebo-Controlled, Biomarker Study |
| Dose | 0, 5, 10, 20, 40, 80 mg/day |
| Endpoints | Reversal of Toxic Cascade |
| Exploratory | Efficacy |

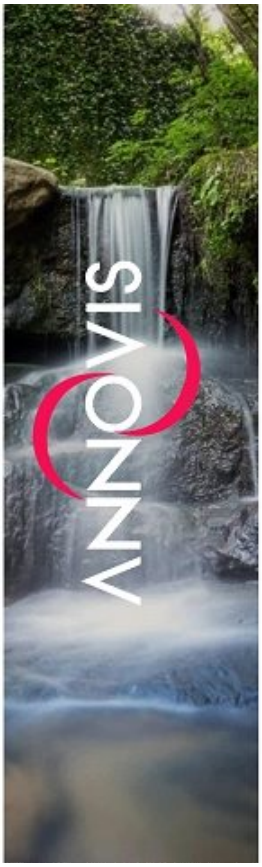
# EFFICACY IN 54 PD PATIENTS – WAIS CODING TEST


Across the dose response the WAIS coding test showed improvements in speed of movement and coordination

# EFFICACY IN 54 PD PATIENTS – MDS-UPDRS Test




The MDS-UPDRS test showed the most improvements at 10 and 20 mg once per day




# SUMMARY AND NEXT STEPS

- Annovis has a novel approach to stop AD and PD
- ANVS401 shows improvements in Phase 2a clinical trials:
  - Cognition in AD patients
  - Motor function in PD patients
  - WAIS coding in AD and PD patients
- This is the first double-blind, placebo-controlled study that shows improvements in AD patients as measured by ADAS-Cog and in PD patients as measured UPDRS
- The successful completion of our Phase 2 clinical trials is providing validation of our approach in two diseases and allows us to begin planning for Phase 3 trials


ANNOVIS
THANK YOU
QUESTIONS?
Symbol: ANVS (NYSE American)