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): July 28, 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 July 28, 2021, as part of the Alzheimer's Association International Conference ("AAIC"), Annovis Bio, Inc. (the "Company") will be presenting new clinical efficacy and biomarker data of its drug ANVS401 during a panel presentation. A copy of the presentation is furnished as Exhibit 99.1.

The information in this Item 7.01, including the attached exhibit, is furnished solely pursuant to Item 7.01 of Form 8-K. Consequently, such information is not deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liabilities of that section. Further, the information in this Item 7.01, including the exhibit, shall not be deemed to be incorporated by reference into the filings of the registrant under the Securities Act of 1933.

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 this presentation and accompanying oral commentary 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 regarding projected timelines of clinical trials, 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 the timing of clinical trials. 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 ("SEC") and elsewhere in our filings and reports with the SEC. These risks, uncertainties and other factors may cause our actual results to differ materially and adversely from what is contained in (or may be implied from) any forward-looking statements. 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 No.	Description
99.1	AAIC Panel Presentation dated July 28, 2021 (furnished herewith)
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

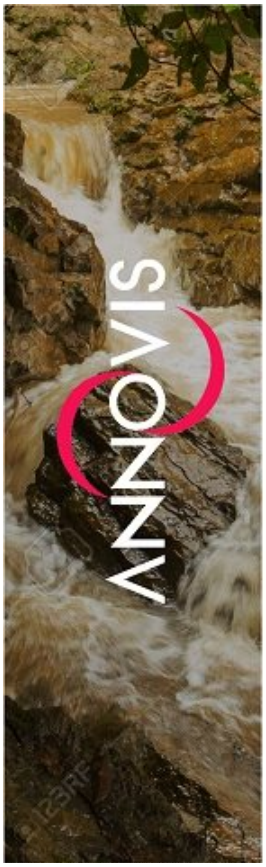
Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ANNOVIS BIO, INC.

Date: July 28, 2021

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

Exhibit 99.1



NEUROTOXIC PROTEINS IMPAIR AXONAL TRANSPORT AND **CAUSE A TOXIC CASCADE**

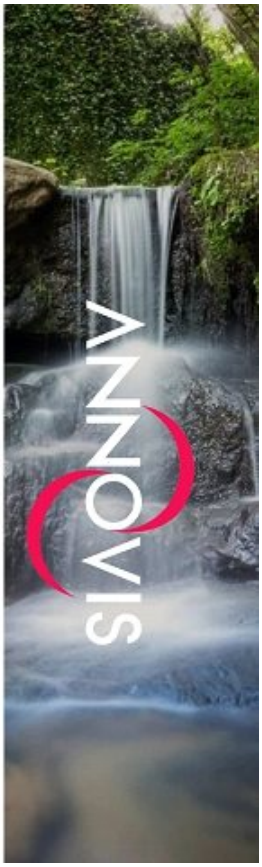
HIGH LEVELS OF NEUROTOXIC PROTEINS

- IMPAIRED AXONAL TRANSPORT
- SLOWER SYNAPTIC TRANSMISSION
- INFLAMMATION
- DEATH OF NERVE CELLS
- LOSS OF COGNITIVE AND MOTOR FUNCTION

Posiphen LOWERS LEVELS OF NEUROTOXIC PROTEINS

- IMPROVED AXONAL TRANSPORT
- INCREASED SYNAPTIC TRANSMISSION
- NO INFLAMMATION
- HEALTHY NERVE CELLS
- IMPROVED COGNITIVE AND MOTOR FUNCTION

Posiphen IMPROVES AXONAL TRANSPORT AND **IMPEDES THE TOXIC CASCADE**



TWO PHASE 2 CLINICAL TRIALS

	AD Trial	PD Trial
Therapeutic Area	Early to Moderate AD	Early to Moderate PD
Patients	14	14 + 40
Phase	2	
Sites	12	
Country	United States	
Design	Double-Blind, Placebo-Controlled, Biomarker Study	
Endpoints	Reversal of Toxic Cascade	
Exploratory	Efficacy	

TIMELINE OF PHASE 2 CLINICAL TRIAL IN AD AND PD

Efficacy and biomarker data as of July 2021.
Additional markers in CSF and plasma are still being measured

A meeting with the FDA to discuss the data from the AD and the PD study as well as from the chronic toxicology in rats and dogs is projected for Fall of 2021

REVERSAL OF TOXIC CASCADE: EFFICACY

Data from first 14 AD and 14 PD patients

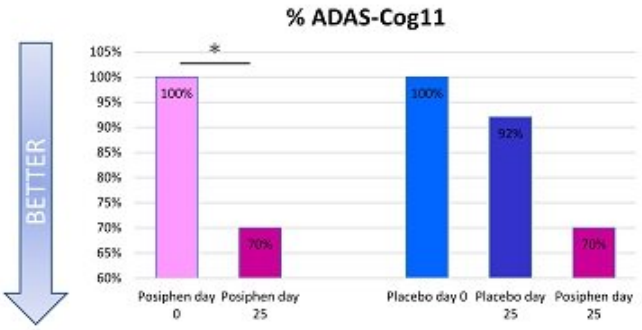
REVERSAL OF TOXIC CASCADE	EXPECTED OUTCOME	ACTUAL OUTCOME	
		AD	PD
Neurotoxic proteins	↓		
Axonal transport	↑		
Axonal damage	↓		
Inflammation	↓		
Synaptic Markers	↓		
Control proteins	0		
Efficacy: WAIS coding	↑	↑	↑
Efficacy: Motor function	↑		↑
Efficacy: Cognition	↑	↑	

BASELINE DEMOGRAPHICS

	ALZHEIMER			PARKINSON		
Patients Enrolled	Placebo (N=6)	Posiphen 80mg (N=10)	Total (N=16)	Placebo (N=5)	Posiphen 80mg (N=10)	Total (N=15)
Age (years)	68.0 (6.87)	72.8 (6.34)	71.0 (6.75)	75.4 (3.13)	65.0 (9.31)	68.5 (9.18)
Male	3 (50.0%)	2 (20.0%)	5 (31.3%)	3 (60.0%)	8 (80.0%)	11 (73.3%)
Female	3 (50.0%)	8 (80.0%)	11 (68.8%)	2 (40.0%)	2 (20.0%)	4 (26.7%)
HISPANIC	4 (66.7%)	5 (50.0%)	9 (56.3%)	2 (40.0%)	0 (0.0%)	2 (13.3%)
CAUCASIAN	2 (33.3%)	5 (50.0%)	7 (43.8%)	3 (60.0%)	10 (100.0%)	13 (86.7%)
WHITE	4 (66.7%)	8 (80.0%)	12 (75.0%)	5 (100.0%)	10 (100.0%)	15 (100.0%)
AFRICAN AMERICAN	1 (16.7%)	0 (0.0%)	1 (6.3%)	0	0	0
ASIAN	1 (16.7%)	1 (10.0%)	2 (12.5%)	0	0	0
NATIVE HAWAIIAN	0 (0.0%)	1 (10.0%)	1 (6.3%)	0	0	0

EFFICACY IN AD PATIENTS – ADAS-Cog11

Data from 14 AD patients

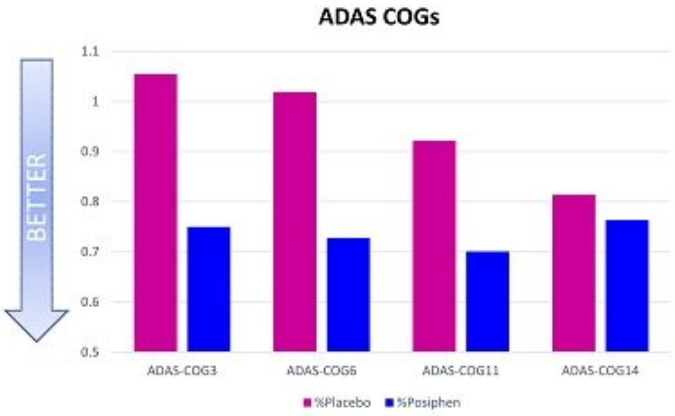


Left: From baseline to 25 days in the Posiphen-treated group, ADAS-Cog11 improved by 4.4 points, a statistically significant improvement of 30% ($p<0.05$).

Right: Posiphen-treated group compared to placebo group at baseline and 25 days showed an improvement of 3.3 points, or 22% ($p= 0.13$).

EFFICACY IN AD PATIENTS – ADAS-Cogs11

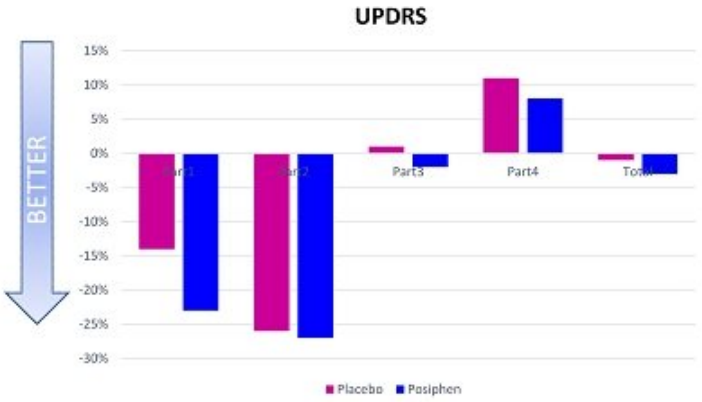
Data from 14 AD patients



Posiphen-treated group showed trends of improvement in all four ADAS-Cog tests performed compared to placebo group.

EFFICACY IN PD PATIENTS – MDS-UPDRS TEST

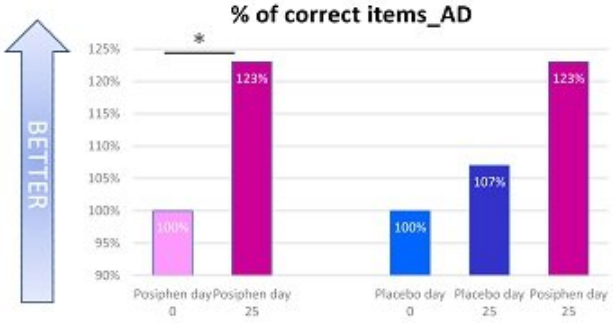
Data from 14 PD patients

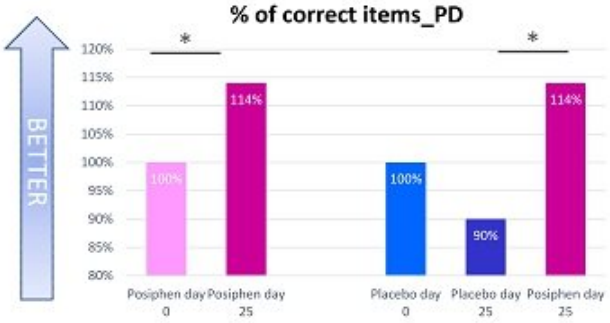


Posiphen-treated group showed trends of improvement in all four parts of UPDRS test compared to placebo group.

EFFICACY IN AD AND PD PATIENTS – WAIS CODING TEST

Data from 14 AD and 14 PD patients





The WAIS coding test measures speed in movement and thinking. Treated AD patients show a 6.6 point and PD patients a 6.1-point improvement in coding after Posiphen treatment.

This is the first double-blind, placebo-controlled study that shows cognitive improvements in AD patients as measured by ADAS-Cog and functional improvements in PD patients as measured by the Unified Parkinson's Disease Rating Scale (UPDRS).

EFFICACY IN AD AND PD PATIENTS - MMSE

MMSE	AD		PD	
	Placebo	Posiphen	Placebo	Posiphen
MMSE Baseline	24.5	25.4	27.6	29.1
25 Days later	25.7	26.2	28.0	29.1
Improvement in MMSE	1.2	0.8	0.4	0.0

While there is a positive trend in AD, the changes in MMSE are not statistically significant.

EFFICACY IN AD PATIENTS – CDR –SUM OF BOXES

CDR	Placebo	Posiphen
Improvement in total score	-1.17	-0.96

In AD patients there are positive trends in orientation, judgement and problem solving, home and hobbies as well as total CDR score, but the data is not statistically significant.

SAFETY SUMMARY

Data from first 14 AD and PD patients

	AD Patients			PD Patients		
	Placebo (N=6)	Posiphen 80mg (N=10)	Total (N=16)	Placebo (N=5)	Posiphen 80mg (N=10)	Total (N=15)
Subjects with any AEs	3 (50.0%)	5 (50.0%)	8 (50.0%)	3 (60.0%)	3 (30.0%)	6 (40.0%)
Number of AEs	4	7	11	5	3	8
Serious AEs	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
AEs that led to Drug Interrupted	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
AEs that led to Drug Withdrawn	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
AEs Suspected Drug Related	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)	0 (0.0%)	1 (6.7%)
AEs Study Procedure	3 (50.0%)	4 (40.0%)	7 (43.8%)	2 (40.0%)	1 (10.0%)	3 (20.0%)
CTCAE Grade 1	3 (50.0%)	4 (40.0%)	7 (43.8%)	3 (60.0%)	3 (30.0%)	6 (40.0%)
CTCAE Grade 2	0 (0.0%)	1 (10.0%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Most AEs were due to the spinal fluid extraction that resulted in headaches and back aches

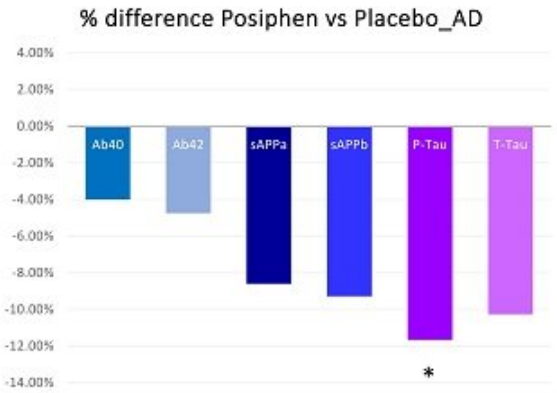
REVERSAL OF TOXIC CASCADE: MARKERS

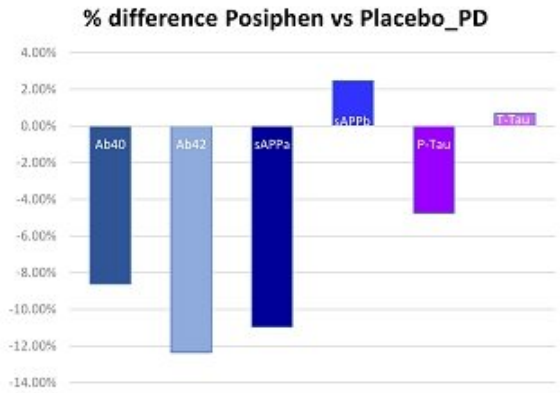
Data from first 14 AD and 14 PD patients

REVERSAL OF TOXIC CASCADE	EXPECTED OUTCOME	ACTUAL OUTCOME	
		AD	PD
Neurotoxic proteins	↓	↓	↓
Axonal transport	↑		
Axonal damage	↓	↓	↓
Inflammation	↓		↓
Synaptic Markers	↓		
Control proteins	0		
Efficacy: WAIS coding	↑	↑	↑
Efficacy: Motor function	↑		↑
Efficacy: Cognition	↑	↑	

STEP ONE OF TOXIC CASCADE
NEUROTOXIC PROTEINS ARE LOWERED

Data from first 14 AD and PD patients





Aβ42/Aβ40 RATIO IN AD AND PD PATIENTS

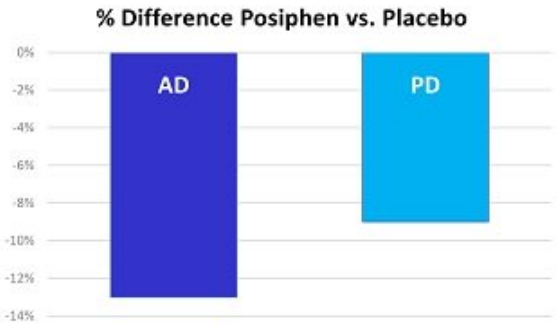
Data from first 14 AD and PD patients

	AD Patients		PD Patients	
	Placebo	Posiphen	Placebo	Posiphen
Baseline	0.064	0.059	0.083	0.097
25 Days	0.064	0.062	0.083	0.097
p-Value		0.0113		

The Aβ42/Aβ40 is **< 0.072** in AD. Our ratios in fact show that AD patients have AD, while PD patients do not. It also shows that in ANVS401 treated patients one month of treatment improves the ratio in a statistically significant fashion.

STEP TWO OF TOXIC CASCADE
NEUROFILAMENT LIGHT IS LOWERED IN AD AND PD PATIENTS

Data from first 14 AD and PD patients



Neurofilament light represents the health of the axon and neuron.

In both Posiphen-treated patient populations, NfL is reduced representing better axonal health.

STEP THREE OF TOXIC CASCADE INFLAMMATION IS LOWER IN PD PATIENTS

Data from first 14 PD patients

Inflammatory Marker	Compared to Baseline or Placebo	% Change from Baseline or Placebo	p-Value
YKL40	within	-22.9	0.032
	between	-55.5	0.097
sTREM2	within	-17.1	0.0001
	between	-42.7	0.001
GFAp	within	-41.6	0.000001
	between	-28.4	0.013

The trial measured four inflammatory markers that are prevalent in the brains of AD and of PD patients.

Each of the inflammatory markers showed statistically significant reduction after 25 days of treatment with ANVS401 compared to baseline and compared to placebo.

WORK IN PROGRESS & SUMMARY

- We have finished treating the additional 40 PD patients and are expecting to complete all the biomarkers of the toxic cascade in the next two months.
- The reversal of the toxic cascade confirms and cements the data seen to date.
- Showing efficacy in AD and in PD patients by two different tests each and showing that the efficacy spans all areas of the ADAS-Cog and the UPDRS strengthens our conclusion that Posiphen is effective in both patient populations.


ANNOVIS
THANK YOU
Symbol: ANVS (NYSE American)