

ANNOVIS BIO, INC.

FORM 8-K (Current report filing)

Filed 06/09/20 for the Period Ending 06/09/20

Address 1055 WESTLAKES DRIVE, SUITE 300

BERWYN, PA, 19312

Telephone 610-727-3913

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Symbol ANVS

SIC Code 2834 - Pharmaceutical Preparations

Industry Biotechnology & Medical Research

Sector Healthcare

Fiscal Year 12/31



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): June 9, 2020

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	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	ng
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 June 9, 2020, Annovis Bio Inc. (the "Company") issued a press release announcing that CEO Maria Maccecchini, Ph.D. and CFO Jeff McGroarty, MBA, CPA, will give a virtual corporate presentation at the June 2020 Virtual Summer Investor Summit taking place online from June 9 to 12, 2020. A copy of the Press Release is attached to this Current Report on Form 8-K as Exhibit 99.1.

Dr. Maccecchini and Mr. McGroarty will give a presentation via webcast on Wednesday, June 10, 2020 at 10:55 a.m. ET, followed by a live Q&A session. A copy of the written presentation is attached as Exhibit 99.2 to this Current Report on Form 8-K. A copy of the presentation will also be available on the Company's website at www.annovisbio.com under "Investors & Media." Investors can register for and access the live webcast at: https://www.webcaster4.com/Webcast/Page/2038/35035.

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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release, dated June 9, 2020.
<u>99.2</u>	Investor Presentation.

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: June 9, 2020 By: /s/ Jeffrey McGroarty

Name: Jeffrey McGroarty Title: Chief Financial Officer

Annovis Bio to Present at the June 2020 Virtual Summer Investor Summit

BERWYN, PA. – June 9, 2020 – Annovis Bio Inc. (NYSE American: ANVS), a clinical-stage drug platform company addressing Alzheimer's disease (AD), Parkinson's disease (PD) and other neurodegenerative diseases, today announced that CEO Maria Maccecchini, Ph.D. and CFO Jeff McGroarty, MBA, CPA, will give a virtual corporate presentation at the June 2020 Virtual Summer Investor Summit taking place online from June 9 to 12, 2020.

Annovis Bio's presentation will be held on Wednesday, June 10, 2020 at 10:55 a.m. ET, followed by a live Q&A session. Investors can register for and access the live webcast at: https://www.webcaster4.com/Webcast/Page/2038/35035.

Dr. Maccecchini and Mr. McGroarty will also be available for one-on-one meetings online. To register for the Virtual Investor Summit, visit: https://virtual-summer-summit.events.issuerdirect.com/signup.

About Annovis Bio

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 expect our treatment to improve memory loss and dementia associated with AD and AD-DS, as well as body and brain function in PD. We have an ongoing Phase 2a study in AD patients and plan to commence a second Phase 2a study in PD and AD patients. For more information on Annovis, please visit the company's website: www.annovisbio.com.

Forward-Looking Statements

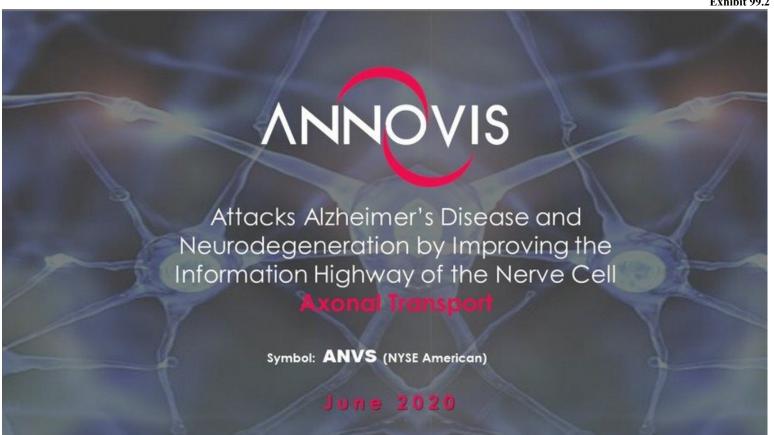
Statements in this press release contain "forward-looking statements" that are subject to substantial risks and uncertainties. Forward-looking statements contained in this press release may be identified by the use of words such as "anticipate," "expect," "believe," "will," "may," "should," "estimate," "project," "outlook," "forecast" or other similar words, and include, without limitation, statements regarding the timing, effectiveness and anticipated results of ANVS401 clinical trials and the approval of any allowances or additional patents. 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. 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, 2019 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.

Investor Relations:

Dave Gentry, CEO RedChip Companies Inc.

407-491-4498 Dave@redchip.com

SOURCE: Annovis Bio Inc.





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 the trading of its shares on the NYSE American market. 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. 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, 2019 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.



HIGHLIGHTS

A novel approach to treat neurodegeneration is desperately needed

- Annovis is developing drugs for Alzheimer's (AD) and Parkinson's disease (PD), including the orphan indication Alzheimer's in Down Syndrome (AD-DS)
- Lead compound, ANVS401, is the only drug to improve axonal transport, the information highway of the nerve cell, by attacking multiple neurotoxic proteins
- Two phase 2a studies
 - AD trial already underway
 - PD trial to be initiated
- Successful completion of the two phase 2a will allow start of two phase 3 studies
- Highly experienced and respected management team, great board and world renowned scientific advisory board



THE STATE OF ALZHEIMER'S DISEASE

- Alzheimer's is the most common cause of dementia, a general term for memory loss and other cognitive abilities serious enough to interfere with daily life.
 Alzheimer's disease accounts for 60 to 80 percent of dementia cases.
- 1 in 6 females and 1 in 11 males have the chance to develop Alzheimer's during the remainder of their lives at age 65.
- From 1998 to 2018 there have been over 500 failed attempts at developing Alzheimer's drugs.
- The sector needs to rethink dementia, develop new approaches and create new drugs.



ALZHEIMER'S DRUG TRIAL FAILURES

Have researchers been on the wrong track with amyloid?

STAT +

66

The idea that sticky brain plaques cause Alzheimer's disease began as an interesting hypothesis and eventually became drug industry dogma. Now, after a string of clinical trial failures, that hypothesis looks less credible than ever. But how did nearly two decades of failure not convince the brightest minds in pharma that it was time to move on?

Damian Garde & Alex Hogan

Amyloid Plaque and Aß is NOT The Only Answer

After amyloid failures, it's time to take a new tack for treating Alzheimer's

Raymond J. Tesi STAT News April 30, 2019



Aducanumab's failure puts pressure on field to look beyond amyloid

Ned Pagliarulo March 22, 2019



ANNOVIS' DRUG TREATS AD AND PD

Chronic and acute brain insults lead to high levels of **neurotoxic proteins**, to **inflammation** and neurodegeneration

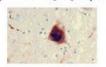
Amyloid β
AD / PD- Aβ Targeting Compounds



Tau
Tavopathies - AD - Tau Targeting Compounds



aSynuclein
PD / AD - aSYN Targeting Compounds



ACTIVATED MICROGLIA = High Inflammation

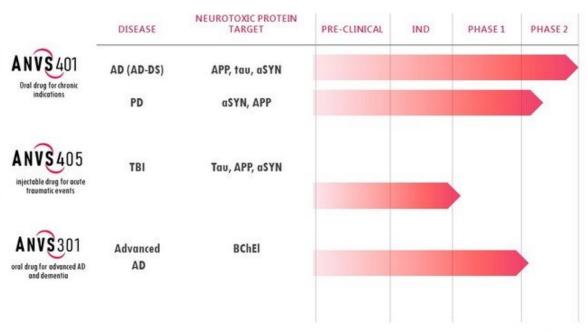


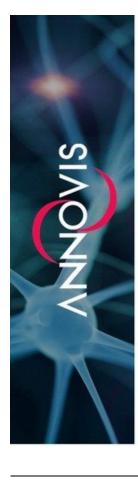
Attacking one neurotoxic protein results in minimal effect

ANV\$401 is the only drug to attack multiple neurotoxic proteins simultaneously



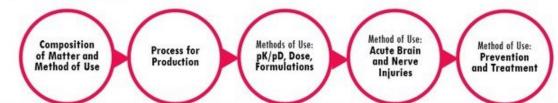
PIPELINE





CORPORATE PATENT ESTATE

Multi-layer strategy

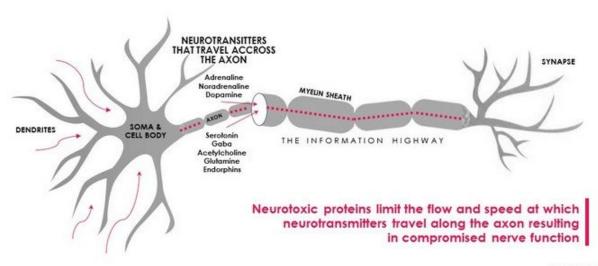


Patent/Application	Subject Malter	Status US	Expiry US
Provisional	ANVS401 to treat viral and bacterial infections of the brain, including Covid19	Pending	2041
PCT	ANVS401 and 405 - Method of use of MOA for prevention and treatment of diseases	Pending	2038
PCT	ANV\$405 - Acute brain and nerve injuries	Pending	2036
PCT	ANVS401 - pK/pD, low doses, formulations Neurodegenerative Diseases	US 10,383,851; 07-2019 EP 2683242; 03-2020	2031
In-licensed patents	Composition of matter, manufacturing, method for treating AD and DS	Granted	2022-25



HOW NERVE CELLS WORK

In healthy nerve cells little packages containing neurotransmitters or nerve growth factors travel unimpaired from the cell body through the axon to the synapse.





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

ANVS401 LOWERS LEVELS OF NEUROTOXIC PROTEINS

IMPROVED AXONAL TRANSPORT

INCREASED SYNAPTIC TRANSMISSION

NO INFLAMMATION

HEALTHY NERVE CELLS

IMPROVED COGNITIVE AND MOTOR FUNCTION

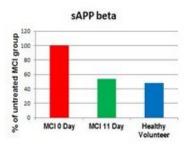


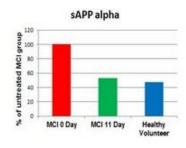
ANVS401 IMPROVES AXONAL TRANSPORT AND IMPEDES THE TOXIC CASCADE

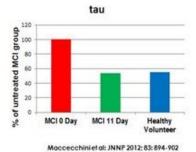


RESULTS IN HUMANS

ANVS401 Lowers Neurotoxic Proteins in Spinal Fluid of MCI Patients







- In this proof of concept study, ANVS401 lowers the levels of APP/Aβ, tau/p-tau and aSYN back to the levels seen in healthy volunteers
- It lowers the levels of the three neurotoxic proteins causing AD and PD



NEURODEGENERATION IS AN AXONAL TRANSPORT DISEASE

Axonal transport is responsible for:

- Neurotransmitters GABA (anxiety), ACh (cognition), dopamine (movement), serotonin (mood)
- Neurotrophic factors NGF, BDNF
- All communication within and between nerve cells

Newly published Nature Review Article (September 2019):

"Axonal transport disruption is linked to human neurological conditions." Retrograde (0.5 frame/sec)

Normal Transport

The Normal Flow and Speed of vesicles carrying BDNF across the axon.



Abnormal Transport

Shows the *Blackage and Slowing* of BDNF across the axon. Black areas demonstrate where transport is slowed due to high levels of neurotoxic proteins.



TREATED WITH ANVS 401

The Flow and Speed of axonal transport is improved.



APP, AB42, C99 — Mobley, UCSD; aSYN — Isacson, Narvard; Lee, U.Penn; Tau — U. Muenich & Zverich; Htt — Mobley, UCSD; TDP43 — Taylor, Northwestern



ANVS401 LOWERS INFLAMMATORY MARKERS

CSF Inflammatory Markers Significantly Decrease After 10 Days of Oral ANVS401 in MCI Patients

Inflammatory Protein	CSF % of Baseline	p-Value
Complement C3	-86.9%	0.0007
MCP-1	-87.5%	0.0007
YKL40	-72.7%	0.0113
sCD14	-26.1%	0.1159
Factor FH*	23.7%	0.4988

* Control Factor

Maccecchini et al: JNNP 2012; 83: 894-902



RESULTS IN ANIMALS

19 animal studies showed that ANVS401 and ANVS405 improved the affected function

ANV\$ 401	ANV\$401 and ANV\$405 increased memory and learning in three animal models:
ANV\$405	 AD tg mice DS trisomic mice TBI rats
ANV\$401	✓ Improved gut motility in PD tg mice
	✓ Stabilized brain chemistry in FTD tau tg mice
ANV\$ 405	✓ Protected retinal cells in acute glaucoma in rats



TWO PHASE 2 CLINICAL TRIALS IN AD AND PD

TRIALS

- AD with 24 patients for one month - ongoing (14 patients treated)
- 2) PD and AD with 68 patients for one month to start in June

ENDPOINTS

Target Engagement

Decrease in neurotoxic protein levels

Pathway Engagement

Increase in neurotransmitters and neurotrophic factors

Lowering of inflammatory proteins Lowering of neurodegeneration markers

Cognitive Outcomes and Functional Outcomes



CLINICAL – OVERVIEW

CRO	Parexel
Therapeutic Area	Early Alzheimer's and Parkinson's Diseases
Phase	2
Design	Double-Blind, Placebo-Controlled, 2-Cohort Biomarker Study
Country	United States
Sites	Up to 15 Sites
Patients	68 Part 1 - Comparison of 14 AD vs 14 PD Patients Part 2 - Dose Response in 40 PD Patients



CLINICAL - SITE UPDATE

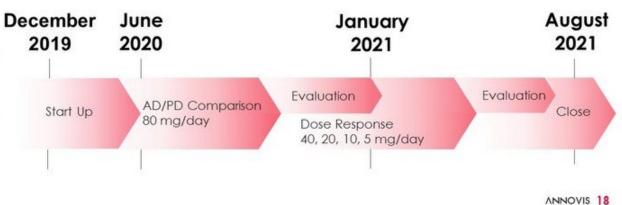




CLINICAL - TIMELINES

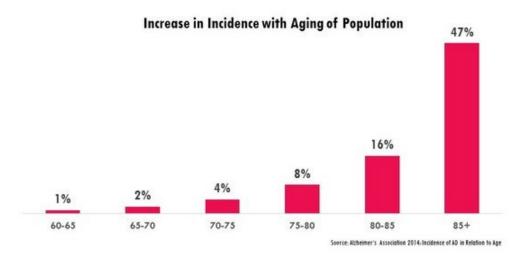
The two-part clinical study is being set up at 15 sites in the US and will begin in June 2020. The AD/PD comparison is projected to be concluded by the end of the year and preliminary data will be available in early 1Q2021

The dose response is projected to be completed by mid summer next year





MARKET PROJECTIONS



Annual sales potential for US and worldwide are over \$100 billion dollars



CHIEF EXECUTIVES AND CHIEF ADVISORS



Maria L. Maccecchini, PhD Founder, President & CEO

Founded Annovis in May 2008 to develop better therapeutics for Alzheimer's, Parkinson's and other neurodegenerative diseases. Was partner and director of two angel groups, Robin Hood Ventures and MidAtlantic Angel Group; Founder and CEO of Symphony Pharmaceuticals/Annovis a biotech company that sold in 2001 to Transgenomic; General Manager of Bachem Bioscience, the US subsidiary of Bachem AG, Switzerland and Head Molecular Biology Mallinckrodt; Dr. Maccecchini did one postdoc at Caltech and one at the Roche Institute of Immunology, her PhD in biochemistry is from the Biocenter of Basel with a two-year visiting fellowship at The Rockefeller University.



Jeffrey McGroarly, CPA, MBA, Chief Financial Officer

Jeff is a financial executive with experience in investor relations, working with analysts, creditors and financial institutions, planning and analysis, capital allocation, SEC communications and reporting, accounting, acquisitions and tumarounds. He is experienced in effectively managing complex projects, building professional relations and developing staff. Mr. McGroarty was previously employed as CFO of Safeguard Scientifics, Interim Controller at Cephalon, Inc., Vice President-Financial Planning and Analysis of Exide Technologies, Inc., and Senior Manager at PWC, Jeff's MBA is from the Wharton School of Business.



Jeffrey Cummings, MD, Chief Medical Advisor

Dr. Cummings completed Neurology residency and a Fellowship in Behavioral Neurology at Boston University. Boston, Massachusetts, US training was followed by a Research Fellowship in Neuropathology and Neuropsychiatry at the National Hospital for Neurous Diseases, Queen Square, London, England, Dr. Cummings was formerly Professor of Neurology and Psychiatry at UCLA, director of the Mary S. Easton Center for Alzheimer's Disease Research at UCLA, director of the Deane F. Johnson Center for Neurotherapeutics at UCLA and director of the Cleveland Clinic Lou Ruvo Center for Brain Health in Las Vegas, Cleveland and Florida, He is past president of the Behavioral Neurology Society and of the American Neuropsychiatric Association. Dr. Cummings has authored or edited 30 books and published nearly 600 peer-reviewed papers.



William Mobley, MD, PhD Chief Scienlific Advisor

Distinguished Professor, Department of Neurosciences Florence Riford Chair for Alzheimer Research and Associate Dean for Neurosciences Initiatives. He is a member of the National Academy of Medicine. His research focuses on the neurobiology of neurotrophic factor actions/signaling and on the hypothesis that malfunction of these mechanisms contribute to neuronal dysfunction in developmental and age-related disorders of the neurosystem.



SCIENTIFIC ADVISORY BOARD



Sidney Strickland, PhD, Chairman Vice President and Dean for Educational Affairs and Research Professor, Patricia and John

Rosenwald Laboratory of Neurobiology and Genetics at Rockefeller University, Dr. Strickland's laboratory investigates how dysfunction of the circulatory system contributes to Alzheimer's and other neurodegenerative disorders. He will serve as the Chairman of Annovis Bio's SAB.

Peter Davies, PhD

Peter Davies received his B.Sc. and Ph.D. both in Biochemistry from the University of Leeds. He was a post-doctoral fellow at the University of Edinburgh, Scotland before joining the staff of the Medical Research Council Brain Metabolism Unit in Edinburgh in 1974, where he began his research on Alzheimer's disease. He is presently the Director of the Litwin-Zucker Research Center.



William Mobley, MD, PhD

Dr. Mobley is Distinguished Professor, Department of Neurosciences Florence Riford Chair for Alzheimer Research and Associate Dean for Neurosciences Initiatives. He is a member of the National Academy of Medicine. His research focuses on the neurobiology of neurotrophic factor actions/signaling and on the hypothesis that malfunction of these mechanisms contribute to neuronal dysfunction in developmental and age-related disorders of the neurosystem.



Dr. Cummings completed Neurology residency and a Fellowship in Behavioral Neurology at Boston University, Massachusetts. US training was followed by a Research Fellowship in Neuropathology and Neuropsychiatry at the National Hospital for Nervous Diseases, London, England. Dr. Cummings was formerly Professor of Neurology, and Psychiatry, Director of Alzheimer's Disease Research and Director of the Center for Neurotherapeutics at UCLA. He was Director of the Cleveland Clinic Lou Ruvo Center for Brain Health in Las Vegas, Cleveland and Florida.



Gregory Petsko, PhD

He is a member of the National Academy of Sciences, the National Academy of Medicine, the American Academy of Arts and Sciences and the American Philosophical Society. His research interests are directed Philosophical Society. His research interests are directed fowards understanding the biochemical bases of neurological diseases like Alzheimer's, Parkinson's, and ALS discovering treatments (especially by using structure-based drug design), that could therapeutically affect those biochemical targets, and seeing any resulting drug candidates tested in humans. He has also made key contributions to the field of protein crystallography.



Rudolph E. Tanzi, PhD

Dr. Tanzi has published over \$00 research papers and has received the highest awards in his field, including the Metropolitan Life Foundation Award, Potamkin Prize, Ronald Reagan Award, Silver Innovator Award, and many others. He was named to TIME magazine's list of TIME100 Most Influential People in the World (2015), and received the Smithsonian American Ingenuity Award, the top national award for invention and innovation. He coauthored the popular trade books "Decoding Darkness". New York Times bestseller, "Super Brain", and international bestseller "Super Genes".





BOARD OF DIRECTORS



Michael B. Hoffman Chairman

Mr. Hoffman is the Founder and Managing Partner of Stone Capital Partners, a private equity firm focused on power and renewable energy. He was Partner of Riverstone, senior managing director at the Blackstone Group and managing director at Smith Barney, Harris Upham & Co. He serves as Chairman of Onconova, Annovis Bio, Curative and is on the Board of Rockefeller University.



Claudine E. Bruck, PhD
Pharmaceutical executive and scientist with strong
entrepreneurial drive. Exhibited successes in
building a therapeutic research unit de novo and building a therapeutic research unit de novo and leading discovery and clinical development of biological (vaccines, biopharmaceuticals) and small molecule medicines as well as an ophthalmic drug portfolio, With creativity and a strong resultsfocus, she is energized to challenge and lead teams. Extensive Pharmaceutical industry experience spans drug discovery and development across several therapeutic.



Maria L. Maccecchini, PhD

Facultive Board Member
Founded Annovis in May 2008 to develop better therapeutics for Alzheimer's, Parkinson's and other neurodegenerative diseases. Founder and CEO of Symphony Pharmaceuticals/Annovis focused on protecting brain cells after stroke. It sold in 2001 to Transgenomic.



Mark is a biopharmaceutical executive with global marketing, business development and sales experience. Currently, Mark is an independent consultant and a member of Robin Hood Ventures, a Philadelphia based angel investor group. Previously, Mark held senior level roles at Pfizer in marketing and commercial development, where he led the successful global launches of Inspira, Revatio, Lyrica and Xeljanz, In his last position, he was Vice President. his last position, he was Vice President Worldwide Marketing, with global responsibility for new product development and in-line marketing for Pfizer's Inflammation Therapeutic Area.



Robert M. Whelan, Jr.

Robert M. Whelan, Jr.
Mr. Whelan brings over 35 years of corporate
finance and investment banking experience to
Annovis' Board of Directors. Since 2001, Mr.
Whelan has been President of Whelan &
Company, LLC, providing financial consulting,
valuation and strategic services to public and
private companies in the technology,
healthcare and alternative energy industries.
From 1999 to 2001, Mr. Whelan served as Vice
Chairman Prudential Valor Expending Course. Chairman, Prudential Volpe Technology Group. Prior to then, Mr. Whelan was a senior executive with Volpe Brown Whelan, a private technology and healthcare investment banking, brokerage and asset management firm.





INVESTMENT SUMMARY

A novel approach to treat neurodegeneration is desperately needed

- The markets for AD and PD drugs are in the multibillions of dollars and growing
- Annovis has a novel solution to stop the course of AD and PD
- ANVS401 improves axonal transport and homeostasis in the brain and recovers the affected function
- The successful completion of our two Phase 2a studies will provide optimal information on target and pathway engagement in AD and PD and allows us to move to two Phase 3 studies

