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Alzheimer’s Disease ...

“... Every 68 seconds someone develops Alzheimer’s”

–The Alzheimer’s Association
Investment Highlights

- Lead product ANAVEX PLUS directed to Alzheimer’s disease, a multibillion dollar, poorly served opportunity
- ANAVEX PLUS poised to enter Phase 2 program
  - Potential to be 1 of 2 FDA registration trials
- ANAVEX PLUS has a de-risked regulatory pathway
  - ANAVEX PLUS is a “cocktail” of the proprietary compound ANAVEX 2-73 and donepezil (generic of Aricept®)
  - ANAVEX 2-73 is an orally available small molecule with a clean Phase 1 data profile
  - Potentially disease modifying; combination shows reversal of memory loss and neuroprotection in several Alzheimer’s disease models including Tg2576
  - Memory model predictive of effects in humans is promising and suggests clear synergistic memory effect
- Further products hold potential for longer-term value creation
  - Pipeline of other CNS and cancer therapeutics candidates offer opportunities for license or partnering agreements
- Sufficient cash on hand and warrant exercise to complete ANAVEX PLUS Phase 2 program
- Publicly traded biopharmaceutical company (OTCQB: AVXL)
  - Anavex Life Sciences Corp. founded in 2006
Stress of Aging ...

- People are living longer, which is good
- But old age often brings a decline in mental capacity
- Researchers are looking for ways to slow or halt such decline
- Stress of aging: Stress in brain cells causes gradual accumulation of damaged proteins causing misfolding of proteins
- Why is misfolding such a threat?
- Snowballing effect – domino effect
- Can we increase the “Quality Control (QC)” in brain cells?

ANAVEX PLUS activates Quality Control (QC) in brain cells by targeting:

Sigma-1 Receptor (Sig-1R), a key cellular survival chaperone protein in neurodegenerative diseases
### Rich Pipeline In Alzheimer’s And Oncology

<table>
<thead>
<tr>
<th>Drug</th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
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<tbody>
<tr>
<td>ANAVEX PLUS</td>
<td>ALZHEIMER’S</td>
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<td>ANAVEX 2-73</td>
<td>ALZHEIMER’S</td>
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<td>EPILEPSY</td>
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<td>STROKE</td>
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<td>ANAVEX 3-71 (AF710B)</td>
<td>ALZHEIMER’S</td>
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<td>PARKINSON’S</td>
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<td>ANAVEX 1-41</td>
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<td>DEPRESSION</td>
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<td>STROKE</td>
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<td>ANAVEX 1079</td>
<td>CANCER (MELANOMA)</td>
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<td>INFLAMMATORY &amp; NEUROPATHIC PAIN</td>
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<td>ANAVEX 1005</td>
<td>CANCER (PANCREAS)</td>
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<td>ACUTE &amp; NEUROPATHIC PAIN</td>
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<td>ANAVEX 1037</td>
<td>CANCER (PROSTATE)</td>
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<td>ACUTE &amp; NEUROPATHIC PAIN</td>
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<td>ANAVEX 1519</td>
<td>CANCER (PANCREAS)</td>
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<td>ACUTE &amp; NEUROPATHIC PAIN</td>
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<td>ANAVEX 1066</td>
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<td>ACUTE &amp; NEUROPATHIC PAIN</td>
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</table>
Strong Management and Scientific Advisory Board

Christopher U. Missling, PhD, MBA

- President & CEO of Anavex
- 20 years of healthcare industry experience within large pharmaceutical companies (Hoechst, Aventis), the biotech industry (Curis, ImmunoGen) and investment banking (Deutsche Bank, Brimberg & Co.)
- MS and PhD from the University of Munich in Chemistry
- MBA from Northwestern University Kellogg School of Management

Michael Gold, MD

- 20 years of experience in clinical development of Alzheimer’s and other nervous system (CNS) drugs
- Vice President of CNS practice at UCB, Inc., a global biopharmaceutical company; previous leadership roles with GlaxoSmithKline, Johnson & Johnson and Bristol-Myers Squibb
- Led several clinical Phase II and Phase III Alzheimer’s disease-related project teams at GSK
- Compound Development Team Leader for Alzheimer's drug Galantamine at J&J, culminating in FDA approval of Galantamine CR (Razadyne® ER)

Jeffrey Cummings, MD

- Professor of Neurotherapeutics and Drug Development in the Neurological Institute, Cleveland Clinic
- Member of the Alzheimer’s Disease Cooperative Study

Paul Aisen, MD

- Professor, Department of Neurosciences, University California San Diego School of Medicine
- Director of the Alzheimer’s Disease Cooperative Study
- Associate Editor of Alzheimer’s Research and Therapy
Strong Management and Scientific Advisory Board

Norman Relkin, MD, PhD

- Associate Professor of Neurology at the Weill Cornell Medical College and Founding Director of the Weill Cornell Memory Disorders
- Over 20 years of clinical trials experience, serving as principal investigator in over 20 therapeutic studies, including multi-center trials he designed

John Harrison, PhD

- Internationally acknowledged specialist for design of human clinical outcome measurement in Alzheimer’s disease and other cognitive impairments
- Honorary Senior Lecturer, Department of Medicine, Imperial College (London, UK)

Ottavio Arancio, MD, PhD

- Associate Professor of Pathology and Cell Biology at the Columbia University Medical Center and The Taub Institute for Research on Alzheimer’s Disease and the Aging Brain, Columbia University
- Over past 10 years, raised more than $25 million in grant funding and published more than 100 peer-reviewed scientific papers

Tangui Maurice, PhD

- Institut National de la Santé et de la Recherche Médicale at INSERM, Montpellier, France
- 20 years in the field of neurosciences, including sigma receptors, normal/pathological aging models for Alzheimer’s and behavioral and molecular neuropharmacology
What is Alzheimer’s Disease (AD)?

- Cells within brain (neurons) transport electrical messages to other parts of body using chemical transmitters (neurotransmitters).
- In Alzheimer’s disease, areas of brain tissue are damaged and some messages do not transmit, causing the symptoms.
- Eventually leads to neurodegeneration, nerve cell death and loss of brain tissue.
- Over time, brain shrinks dramatically, affecting nearly all functions.

Sources: Alzheimer’s Association; examiner.com
Alzheimer’s Disease Stages

<table>
<thead>
<tr>
<th>Stages of Alzheimer’s</th>
<th>Increased burden</th>
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<tbody>
<tr>
<td>Terminal</td>
<td>Loss of speech; locomotion, consciousness; death</td>
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<tr>
<td>Very Severe</td>
<td>Full-time care needed; institutionalized</td>
</tr>
<tr>
<td>Severe</td>
<td>Can no longer take care for self; incontinent, depressed</td>
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<tr>
<td>Moderate</td>
<td>Can no longer manage personal affairs; agitated, care needed</td>
</tr>
<tr>
<td>Mild</td>
<td>Family and friends notice problems</td>
</tr>
<tr>
<td>Appears Normal</td>
<td>Mild function deficit – ‘forgetful’</td>
</tr>
<tr>
<td>Normal</td>
<td>No noticeable cognitive decline</td>
</tr>
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</table>

Sources: Alz.org; ABPI
Alzheimer’s Market Overview

Forecast of Alzheimer's Disease Prevalence in the US

<table>
<thead>
<tr>
<th>Year</th>
<th>Prevalence</th>
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<tbody>
<tr>
<td>2000 (est)</td>
<td>4.5 Million</td>
</tr>
<tr>
<td>2030 (est)</td>
<td>8.6 Million</td>
</tr>
<tr>
<td>2050 (est)</td>
<td>16.0 Million</td>
</tr>
</tbody>
</table>

Changes in Number of Deaths (All Ages) Between 2000 and 2010

- Breast Cancer: -68%
- Prostate Cancer: -2%
- Heart Disease: -8%
- Stroke: -16%
- HIV: -23%
- Alzheimer’s Disease: -42%

Aging strongest predictor
- 40 million Americans are over the age of 65
- 80 million Americans over 65 by 2040

Diagnosis accelerating
- 5 million+ Americans currently diagnosed

Sources: Alzheimer’s Association, ICAD, UC Davis Alzheimer’s Disease Center, IMS
Significant Market Potential

- $200 billion spent caring for those suffering from Alzheimer’s disease; expected to reach $1.1 trillion by 2050, given the rapid rise in cases
- U.S. FDA approved four drugs that only temporarily slow worsening of symptoms for about 6 to 12 months, for about half of patients
- $4 billion annual sales for leading drug Aricept® (donepezil now generic)
- $6 billion total drug sales

Donepezil  Rivastigmin  Galantamine  Memantine

More effective treatments will create a multibillion dollar product market opportunity

Source: Alzheimer’s Association, ICAD, UC Davis Alzheimer’s Disease Center, IMS, Orange Book
Current Challenges in Alzheimer’s

- Recent failures of both “bapi” (Elan, J&J, Pfizer) and “sola” (Eli Lilly) provide evidence that treating AD may not be as simple as removing Abeta plaques in the brain.

- Free-floating particles of Abeta (oligomers) damage brain cells in conjunction with hyper-phosphorylation of Tau and inflammation and mitochondrial dysfunction.

- Healthy brain cells actually have ability to clear Abeta proteins very quickly when not distressed.

- A further “upstream” neuro-protective strategy may help the brain to preserve this ability in distressed cells.

- Hence, targeting multiple AD pathways simultaneously at different levels of the disease stage might be needed ...

- ... ANAVEX PLUS is doing that ...
Accumulation of misfolded proteins in the brain is a common feature of most neurodegenerative diseases, and misfolded proteins cause stress, leading to neuronal impairment.

Sig-1R is a membrane protein chaperone only upregulated in case of cell stress.

Sig-1R prevents accumulation of misfolded proteins by consigning them to degradation, hence Sig-1R plays a key role in cellular survival.

Sig-1R upregulation through ANAVEX PLUS has therapeutic potential in protein conformation diseases characterized by chronically misfolded pathological proteins (e.g. AD, PD, LBD, FTLD, ALS and more).

Three way mode of action of mixed muscarinic / Sig-1R agonist: Ca\textsuperscript{2+} modulation, reducing mitochondrial dysfunction and oxidative stress, hence indirectly targeting also both Abeta and Tau.

Schnell et al, J. Biol. Chem. 2013, 288:21448-21457
ANAVEX PLUS Mechanism of Action in Alzheimer‘s:

- Primary effect of Abeta toxicity: after staying in neurons for too long induction of cell stress
- Endogenous Sig-1R expressed to reduce cell stress level
- Chronic cell stress possibly causing Alzheimer‘s disease (high correlation with age)
- Hence increasing Sig-1R through Sig-1R agonist ANAVEX PLUS directly reduces chronic cell stress and Alzheimer‘s symptoms
ANAVEX 2-73 Significantly Reduces Pathology in Transgenic Alzheimer's Disease Model Tg2576

- 10 month-old Tg2576 and WT male mice administered p.o. (oral) with tap water or ANAVEX 2-73 (3 mg/kg/day)
- After 2 months, tested for place learning in the water-maze
- Acquisition of memory profiles (a), time in T quadrant (b) and swimming speed during the probe test (c)
- N = 6-12 per group
- * p < 0.05, ** p < 0.01 vs. V-treated WT mice; # p < 0.05, ### p < 0.001 vs. V-treated Tg2576 mice

Presented at SfN Neuroscience Meeting 2013
... ANAVEX PLUS Clear Synergistic Effect of ANAVEX 2-73 with Aricept® (Donepezil) by 80%

Cursor-on-scale representation of the relative protection induced by ANAVEX2-73 and donepezil or memantine, and their combination (Mix) in Aβ25-35-treated mice

- ANAVEX PLUS: Potential novel combination drug for Alzheimer’s

Presented at AAIC 2012
ANADEX PLUS: Compelling Commercial Opportunity Both as Symptomatic as well as Potentially Disease-Modifying Agent

- ANAVEX PLUS: Combination of ANAVEX 2-73 “Plus” Aricept® (donepezil) = Potential novel combination drug for Alzheimer’s

- Lower clinical trial risk since one compound Aricept® (donepezil) is already on market, selling $4 billion annually

- Potentially disease modifying ANAVEX 2-73: Able to reverse memory and learning deficits and protect nerve cells from neurodegeneration and cell death in animal models

- Aricept® (donepezil) is now generic

- Patent application filed for combination of ANAVEX PLUS: If granted, protection until at least 2033
Translation Pre-Clinical Data to Clinical Data: Understanding The Disconnect Between Rodents and Humans ...

... Big Pharma uses a predictive patent protected calibrated Quantitative Systems Pharmacology model (QSP):

- **PF-04995274 (Pfizer)** in AD – Predicted clinical outcome of cognitive worsening in POC human study
- **JNJ37822681 (JNJ)** in schizophrenia – Predicted clinical outcome of motor side liability effect in human schizophrenia patients
- **Ocaperidone (JNJ)** in schizophrenia – Predicted clinical efficacy and side-effect outcome in humans schizophrenia patients qualitatively
- **Dimebon (Medivation)** in AD – Partially provide post-hoc explanation for different clinical efficacy outcomes in Phase II and Phase III in human AD patients, based on genotypes
- **H3 antagonism in AD (Abbvie-Merck)** – Prediction of loss of efficacy over time in ADAS-Cog outcome for Phase II study
- **Vabicaserin (Pfizer)** in schizophrenia – Predicted quantitative clinical estimate of PANSS Total in Phase II study in schizophrenia patients
- **MEM3454 (Roche)** in schizophrenia – Provided explanation of clinical outcome in Phase II POC study in Cognitive Impairment based on imbalance in co-medication

Source: In Silico Biosciences
ANAVEX PLUS Anticipated ADAS-Cog Response of 7 Points at 12 Weeks and 5.5 Points at 26 Weeks – More Than 2X Aricept® (Donepezil) Alone

- Humanized calibrated realistic cortical network computer model
- Confirmed pre-clinical unexpected synergy between ANAVEX 2-73 and Aricept® (donepezil)
- Model focused only on symptomatic effects and Sig-1R effect was not yet even factored in

Lower clinical trial risk since one compound (donepezil) already on the market, selling $4 billion annually

AV2-73 augmentation to 5 mg Donepezil (ADAS-Cog)

Changes in ADAS-Cog

\[ \Delta = 7 \]

\[ \Delta = 5.5 \]

Placebo 12 wk  Placebo 26 wk

M2 mAChR Target Engagement (%)
ANAVEX PLUS: Integrated Phase 1b/2 Clinical Development Plan

- Advantage: Minimizes timelines and budget
- Both duration and size of trial would allow for proper data readout
- With potential for next trial being the pivotal Study

<table>
<thead>
<tr>
<th>Phase 1b/2a Study</th>
<th>Phase 2/3 Study*</th>
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<tbody>
<tr>
<td>Mild-(moderate) AD patients (~40)</td>
<td>Mild-(moderate) AD patients (300)</td>
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<tr>
<td>ANAVEX 2-73 Dose A-E</td>
<td>ANAVEX 2-73 Dose A /DPZ (n=100)</td>
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<tr>
<td>ANAVEX 2-73 Dose A-E /DPZ</td>
<td>ANAVEX 2-73 Dose B /DPZ (n=100)</td>
</tr>
<tr>
<td>Donepezil (DPZ)</td>
<td>Donepezil (DPZ) (n=100)</td>
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Start: Mid 2014 or later
Enrollment of patients accelerated since identified patients already on donepezil
Endpoint: Determine a tolerated repeat dose and extend safety exposure for ANAVEX 2-73/DPZ; determine extended exposure pharmacokinetics;
Evaluation of exploratory efficacy (cognitive measures) and other test batteries

Start: after 1b/2a Study
Duration: 6/12 months
Endpoint: Evaluation of efficacy (ADAS-Cog) with evaluation of biomarkers; extended safety data
Potential for Big Pharma partnership

*Potential for first registration Study
Phase 1 Single Dose Completed

- Single ascending dose study of ANAVEX 2-73 in healthy human volunteers
- Randomized, placebo-controlled study
- Healthy male volunteers between the ages of 18 and 55 received single, ascending oral doses over the course of the trial
- **Objectives:** Define maximum tolerated dose, assess pharmacokinetics (PK), clinical and lab safety
- **Results:**
  - Dosing from 1-60 mg
  - Maximum tolerated dose 55-60 mg; above the equivalent dose shown to have positive effects in mouse models of AD
  - Well tolerated below the 55-60 mg dose with only mild adverse events in some volunteers
  - Observed adverse events at doses above the maximum tolerated single dose included headache and dizziness, which were moderate in severity and reversible. These side effects are often seen with drugs that target central nervous system (CNS) conditions, including AD
  - No significant changes in blood safety measurements
  - No changes in ECG
  - Favorable PK profile
    - Rapid absorption into blood
    - Dose proportional kinetics
Financial Summary

- Shares Outstanding*: 38.3 Million
- 52 Week Range*: $0.23-$0.87
- Cash @ 3/31/14: $9.2 Million
- Cash burn 1: ~$60k/ mo. corporate
- Cash burn 2: ~$500k/ mo. w/ trials
- Symbol: AVXL

*As of 5/14/2014
Near-term Milestones

- Secure cGMP manufacturing for drug candidate trial supplies – 2Q 2014
- Enroll first patient in Phase 1b/2a study – 2014
  - Safety and exploratory efficacy
- Enroll first patient in Phase 2 study – 2015
  - Ongoing safety and efficacy
  - Potential for first registration study
- Report data from Phase 1b/2a study – 1H 2015
- Complement current pipeline through in-licensing – ongoing
- Advance preclinical research with candidates ANAVEX PLUS, ANAVEX 2-73, ANAVEX 3-71 and ANAVEX 1-41 in Parkinson’s disease and ALS – 2014
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... Anavex is working on a potential solution.
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