

Alzhyne Limited

Private Equity | Australia

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VIRIATHUS[®]

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Company Description:

Alzhyne Limited is developing novel drugs and diagnostics for the effective treatment of Alzheimer's disease. This disease, associated with progressive memory loss and brain cell death, mainly affects the elderly; about 10% of those past the age of 65 have Alzheimer's disease, with risk doubling every five years. Alzhyne has identified a family of peptides that specifically neutralize the damaging potential of beta-amyloid in the brain. Accumulations of beta-amyloid are believed to form senile plaques and cause brain cell death. In proof of concept and other studies, Alzhyne's lead drug candidate ANA-5 was found to significantly inhibit beta-amyloid-induced neurotoxicity in animal models and the Company is moving forward with the development of an orally available analog of ANA-5 for the treatment of Alzheimer's disease.

Overview Report Highlights:

- Huge, growing market characterized by unmet medical needs**

Approximately 18 million individuals and their families worldwide are affected by Alzheimer's disease, and patient numbers are projected to double by 2025. At present, there is no vaccine or cure for Alzheimer's disease. Drugs that temporarily treat disease symptoms generate annual sales of US\$2.5 billion and industry experts believe the potential market for a disease cure could easily reach US\$25 billion.

- Alzhyne's technology advantage**

Alzhyne has identified peptides that specifically target beta-amyloid, a protein critical to the development of Alzheimer's disease. While some competitor drug candidates also neutralize beta-amyloid, these products indiscriminately act upon other important brain enzymes as well, causing adverse side-effects.

- Internationally recognized research team**

Professor Ralph Martins, an internationally recognized leader in Alzheimer's disease research, directs Alzhyne's research activities. Professor Martins was the first to propose and demonstrate that the Alzheimer's brain is under oxidative stress. His discoveries set the course of current research into new disease treatments. Professor Martins has published over 110 scientific papers and reviews on Alzheimer's disease.

- Blood test for early disease detection targeted prior to 2011/2012**

Alzhyne will initially focus on developing a serum-based test for early detection of Alzheimer's disease. The Company is partnering with U.K.-based Senexis on this project and believes development of a diagnostic test is potentially achievable as a key milestone prior to the Company's planned 2011/2012 IPO. Experts peg the potential market for a diagnostic test for Alzheimer's disease at US\$1.0 billion.



Financial Data:

Price:NA
 Market Capitalization (mln):NA
 Shares Outstanding (mln):39.98
 Options Outstanding (mln):4.87
 Current Cash & Short Term Investments:0.21
 Cumulative Capital Raised (5 years):1.56
 Exchange:NA

Future Milestones (12-24 months):

- Complete development of diagnostic blood test for the early detection of Alzheimer's disease.
- Establish clinical relevance and validation of beta-amyloid blood assay in Alzheimer's patient population.
- Complete lead optimization for ANA-5.
- Begin proof of concept transgenic animal study of oral analog of ANA-5.
- Complete and publish results of beta-amyloid PET imaging study using radio-labeled analog of ANA-5 as the molecular imaging agent.

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Balance Sheet (AUD)	Jun 08
Cash	\$22,437
Working capital	\$58,532
Current Ratio	5.5x
Long-Term Obligations	\$100,000
Equity	\$26,859

P&L Data(000)	Jun 05	Jun 06	Jun 07	Jun 08
Revenues	.272	3.36	2.75	2.81
Expenses	69.8	303.7	255.3	203.0
Operating Loss	69.6	307.1	255.3	202.9
Net Loss	69.6	307.1	134.4	158.7

Margin: (%)	Jun 05	Jun 06	Jun 07	Jun 08
Gross Margin	NM	NM	NM	NM
Operating Margin	NM	NM	NM	NM
Net Margin	NM	NM	NM	NM

Alzhyne Limited

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Information Overview

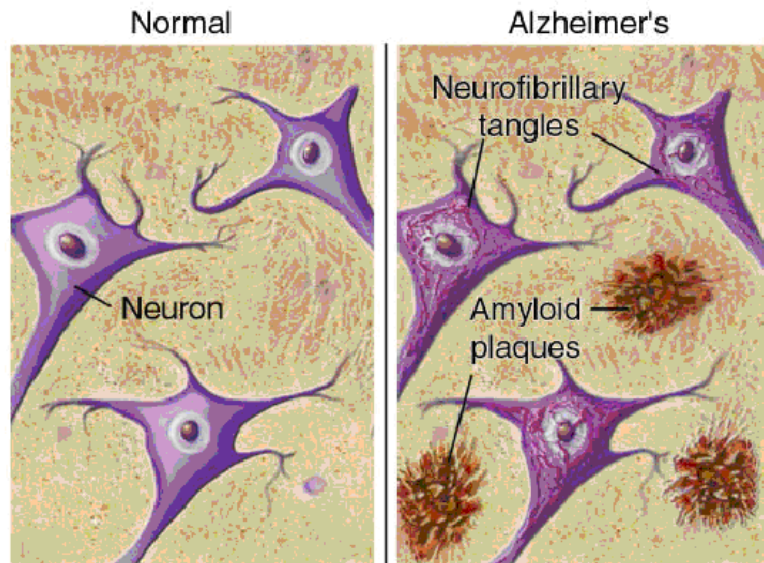
Alzhye Ltd (Alzhye) is an Australian public unlisted company limited by shares engaged in the discovery and development of novel treatments and early-stage diagnostics for the prevention and cure of Alzheimer’s disease. The Company is building a balanced portfolio of pre-clinical and early-stage clinical drug candidates, which it intends to develop and then license to large pharmaceutical companies.

Alzhye is researching treatments and diagnostic tests for Alzheimer’s disease, an illness characterized by the presence of insoluble deposits (“senile plaques”) in regions of the brain associated with cognitive function. Senile plaques are formed from beta-amyloid, a naturally occurring protein extremely toxic to brain cells if produced at high levels. There is considerable evidence indicating overproduction and accumulation of beta-amyloid is central to the pathogenesis of Alzheimer’s disease and the cause of brain cell destruction.

Overproduction and accumulation of beta-amyloid, a naturally occurring protein in the brain, is believed to be central to the pathogenesis of Alzheimer’s disease.

Alzhye’s Technology

Beta-amyloid can exist in many forms, with the monomeric form being soluble. However, beta-amyloid aggregates readily to form dimers and oligomers of increasing size. Naturally occurring metals in the brain (copper, iron and manganese) have been shown to accelerate the aggregation of beta-amyloid. Solubility of beta-amyloid declines when aggregation increases, leading to the formation of plaques and fibrils. The exact mechanism by which beta-amyloid exerts damage is unclear, but the data suggests that beta-amyloid –induced oxidative stress is an underlying cause of Alzheimer’s disease. This may happen because beta-amyloid accumulation in neuronal cells results in increased hydrogen peroxide and the production of reactive oxygen species (ROS) that evoke neurotoxicity.



Pathology of Alzheimer’s disease

Superoxide dismutases (SOD) are enzymes that catalyze the breakdown of superoxide into hydrogen and peroxide. As such, these enzymes are an

important antioxidant defense in cells exposed to oxygen. SOD helps the body use zinc, copper and manganese. However, high levels of SOD sensitize cells to oxidative stress through the overproduction of hydrogen peroxide. As a result, toxicity associated with beta-amyloid is largely dependent on SOD-like activity.

Fundamental to Alzhyne's drug development program is that observation that human beta-amyloid is much more neurotoxic than rat beta-amyloid, which differs only at amino acid residues 5, 10 and 13 (a region referred to as the SOD-like site). Moreover, this site is similar to the site on human beta-amyloid protein that interacts with metal ions. Alzhyne is developing compounds that neutralize beta-amyloid catalytic production of hydrogen peroxide by selectively targeting and binding to the SOD-like site on human beta-amyloid. By binding to the SOD-like site, these compounds prevent beta-amyloid from eliciting damaging effects on the brain.

Through screening, Alzhyne has discovered a family of 25 peptides that bind to the SOD-like site of human soluble beta-amyloid. These peptides share a strong consensus sequence of four to six amino acids, suggesting it should be possible to develop low molecular weight imitation peptides or small molecules that mimic their action. Having already identified therapeutic peptides, Alzhyne's next step is to create orally available, non-peptide mimetics through rational drug design. Alzhyne plans to create a library of up to 50 compounds that will be synthesized under contract for hit-to-lead screening. These will comprise a portfolio of promising new drug candidates that prevent neurotoxicity associated with Alzheimer's disease.

The Company has already identified two potentially therapeutic peptides, ANA-1 and ANA-5, which have demonstrated the ability to significantly inhibit activity SOD-like activity and hydrogen peroxide production, thus protecting against beta-amyloid-induced cell death. In proof of concept studies using mouse models of Alzheimer's disease, ANA-5 was shown to reduce beta-amyloid plaque levels by 27% in the brains of treated animals.

Alzhyne has identified novel compounds that selectively target beta-amyloid. The advantage of this selectivity is fewer side-effects, since unrelated metabolic processes are not affected.

Advantages of Alzhyne's Approach

Several drug companies are developing agents that reduce beta-amyloid by inhibiting the enzymes that catalyze its production. Although many drugs have been discovered, none have been successful in human clinical trials due to their undesirable side-effects. Side-effects occur because enzymes that catalyze the production of beta-amyloid also catalyze the metabolism of other proteins. Non-selectively inhibiting their action reduces beta-amyloid production but also blocks other metabolic processes necessary for good health.

A major advance in Alzheimer's disease research was the discovery of vaccines that target beta-amyloid directly and enhance its clearance. Animal studies yielded exciting results, showing for the first time that beta-amyloid deposits could be removed and cognition in treated animals significantly improved. However, human clinical study results were disastrous, with a sizable percentage of patients treated with the vaccines developing inflammation of the brain.

A more recent approach, pioneered by Melbourne-based Prana Biotechnology (NASDAQ:PRAN and ASX:PBT), uses Clioquinol, a metal

chelator (i.e. binding agent that suppresses chemical activity) to neutralize beta-amyloid toxicity. Beta-amyloid requires copper and zinc to generate hydrogen peroxide; by chelating these metals, catalytic activity is inhibited. Although Clioquinol is efficacious in neutralizing beta-amyloid, its action is non-specific, and side-effects occur because brain enzymes that bind metal ions are also affected.

Alzhyne's innovative approach is to neutralize beta-amyloid through compounds that selectively attach to the metal binding site on beta-amyloid using novel, proprietary methodology. *In vitro* studies of Alzhyne's peptides showed them equipotent with Clioquinol in reducing beta-amyloid toxicity and also specific in their action, affecting only the intended target. Animal studies confirmed the ability of Alzhyne's peptides to enhance beta-amyloid clearance from the brain. Overall, Alzhyne's compounds were shown to be highly specific in their targeting and effective in clearing neurotoxins from the brain. As a result, they hold exceptional promise as a new class of therapeutic agents for the treatment of Alzheimer's disease.

Research Capabilities

Alzhyne has established efficient research capabilities for the functional validation of its compounds in both *in vitro* and *in vivo* models of Alzheimer's disease. Most of the Company's research and development activities are conducted under research agreements with Edith Cowan University, the University of Western Australia and the McCusker Foundation, co-facilitators of the Sir James McCusker Research Unit for Alzheimer's Disease, Inc., (McCusker Research Unit). Assistance from the McCusker Foundation, a charitable organization, is largely tapped to continually improve/upgrade facilities and equipment, ensuring a state-of-the-art research infrastructure.

The Company's proprietary technologies are the result of discoveries made by Alzhyne's Chief Scientific Officer, Professor Ralph Martins, and his 25+- member research team. The research team has developed proprietary expertise in techniques and procedures in-house, including acute measurement of beta-amyloid concentration and toxicity, and modification of conventional techniques for identifying drug candidates. Many of their techniques are known to only a handful of laboratories around the world.

Professor Ralph Martins is an internationally recognized leader in Alzheimer's disease research. He is the Foundation Professor of Aging and Alzheimer's Disease at Edith Cowan University and the Founding Director of the Center of Excellence for Alzheimer's Disease Research and Care. Professor Martins was the first to propose and demonstrate that the Alzheimer's-affected brain was under oxidative stress from a build-up of free radicals caused by increases in soluble beta-amyloid. He has published over 110 scientific papers and reviews on Alzheimer's disease. His discovery of increased beta-amyloid in the Alzheimer's brain has become the focal point of global research into new Alzheimer's disease treatments.

Professor Martins and his team have established strong ties with other Australian and international Alzheimer's disease research groups and with clinical care providers to Alzheimer's patients. Alzhyne gains access to valuable clinical sources through its relationship with Dr. Roger Clarnette, a long-time collaborator of Professor Martins and the Clinical Trials Coordinator at the McCusker Research Unit. Dr. Clarnette has over ten

18 million patients and their families are currently affected by Alzheimer's disease, and their numbers are projected to double by 2025.

years experience conducting clinical trials in Alzheimer's disease. Pfizer, Novartis, Eisai and other international pharmaceutical companies have utilized Dr. Clarnette's 2,000 strong Alzheimer's disease patient cohorts to test new drugs in FDA-compliant clinical trials.

The Company's technologies are protected by patents, patent applications and trade secrets. Alzhyme's intellectual property encompasses compounds, compositions of matter, and methods and uses for treating Alzheimer's disease and related dementias. Professor Martins and his team believe their highly targeted approach has significant advantages over existing drugs and other development-stage drug candidates. The Company has an Australian patent for its screening methods and identified agents, has patents pending in the U.S. and Europe, and has applied for an international patent for its improved peptide composition.

Alzheimer's Disease Market

The worldwide market for Alzheimer's disease treatments is enormous and expanding rapidly. Approximately 1% of the world's population is already affected by this disease. At present, there are an estimated 18 million Alzheimer's sufferers worldwide, and their numbers are projected to double by 2025 due to the aging of the world's population. Alzheimer's disease affects all members of society and is not linked to any particular social class, gender, ethnic group or geographic location.

Currently, the only approved treatment consists of drugs that temporally ease symptoms of the disease. These drugs are generally useful for only a few months, becoming ineffective as the disease advances. The current market for Alzheimer's disease drugs is estimated at US\$2.5 billion. There are no approved diagnostic tests for early detection of the disease, no approved vaccines and no cure.

Alzhyme's Business Strategy

By pursuing an integrated pipeline approach encompassing diagnostic tests, imaging agents and disease-modifying drugs, Alzhyme expects to meaningfully impact the Alzheimer's disease market, ease the suffering of millions of patients and create a future in which Alzheimer's disease is no longer a death sentence. Alzhyme expects to achieve these objectives by:

- **Adding value to its technologies in staged processes**, which allows the Company to focus its capital and resources on diagnostic tests and disease-modifying agents having the greatest likelihood of success;
- **Establishing partnerships and collaborations**. The Company has partnerships with the Australian Nuclear Science and Technology Organization (ANSTO), the Commonwealth Scientific and Industrial Research Organization (CSIRO), Edith Cowan University and the Sir James McCusker Foundation for Alzheimer's Disease Research, Inc. In addition, Alzhyme is working with Senexis (United Kingdom) to develop a serum-based diagnostic test for Alzheimer's disease;
- **Building a balanced portfolio** consisting of pre-clinical and early-stage clinical compounds and diagnostics, which together create near-term and longer-term revenue opportunities;
- **Avoiding the risks associated with a single product** by developing diagnostic tests, disease-modifying therapeutics and

Through relationships with universities, government agencies and other partners, Alzhyme gains access to state-of-the-art research facilities and related infrastructure.

imaging agents and pursuing opportunities to in-license late-stage compounds;

- **Maintaining a focus on value creation** through ongoing product development and capitalizing on licensing opportunities. Alzhome plans to monetize the value of its pipeline through an Initial Public Offering in 2011/2012.

Through the Company's relationships with universities, foundations, government agencies and corporate partners, Alzhome gains access to leading-edge research facilities and infrastructure that would cost millions of dollars to reproduce. Alzhome was established through an initial private investment by its founding shareholder Mr Harold Clough, who is Chairman of the Company. His private family company McRae Technology Pty Ltd continues to support Alzhome's research. In the last five years, Alzhome has invested approximately AU\$1.56 million in advancing its discoveries through pre-clinical and proof of concept studies. The Company seeks to raise at least AU\$3.0 million through a stock offering, and plans to use the funds to further pre-clinical development of its therapeutics, blood test and imaging agent.

Because of rising R&D costs and declining product life cycles within the pharmaceutical industry, demand for strategic product acquisitions and/or in-licensing is likely to increase significantly over the next five years. With its technology advantage, internationally recognized research team, and focus on a huge market with unmet medical needs, Alzhome is well-positioned to attract industry partners for a high-value research collaboration or potential acquisition.

Development Strategy

Alzhyne is building a portfolio of pre-clinical and early-stage clinical drug candidates for the treatment of Alzheimer's disease and diagnostic tests for detecting the disease in its early stages. The Company plans to self-fund pre-clinical and early clinical development and then seek licensing agreements with industry partners for clinical trials, regulatory approval and product commercialization.

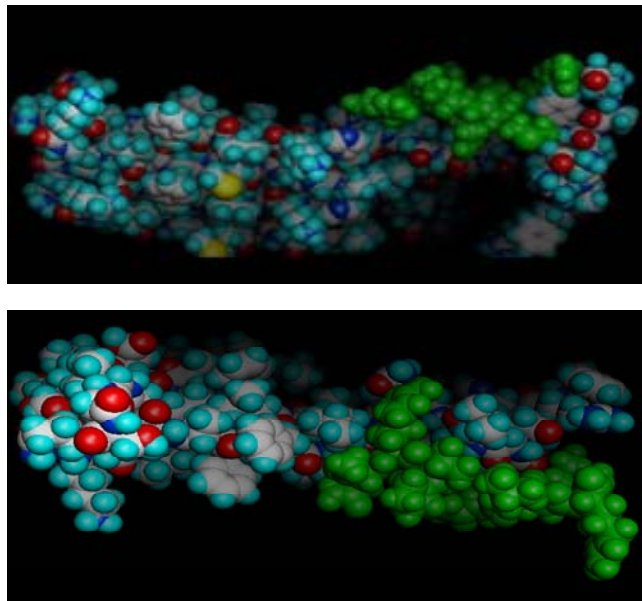
Disease-Modifying Agents

Alzhyne has used its proprietary intellectual property to identify therapeutic peptides that specifically neutralize the damaging potential of beta-amyloid. Senile plaques in the Alzheimer's brain are composed of beta-amyloid, and there is considerable evidence indicating overproduction and accumulation of beta-amyloid is central to the pathology of Alzheimer's disease. The theory, that beta-amyloid overproduction leads to the destruction of brain cells and deterioration of mental function, is known as the Amyloid Cascade Hypothesis.

In zebrafish models, Alzhyne's lead compounds, ANA-1 and ANA-5, were found to significantly inhibit beta-amyloid-induced neurotoxicity.

Alzhyne has used innovative screening of focused compound libraries and medicinal chemistry to identify novel peptides that target soluble beta-amyloid. Screening has led to the discovery of a family of 25 peptides that specifically neutralize beta-amyloid's damaging effects by binding to the SOD-like site on human soluble beta-amyloid.

One of these enriched peptides (ANA-1) was found to significantly reduce human beta-amyloid SOD-like activity and hydrogen peroxide production, and protect against beta-amyloid-induced cell death. Alzhyne then used computer-based *in-silico* modeling to modify ANA-1 and create a second lead peptide (ANA-5), which also inhibits SOD-like activity and beta-amyloid-induced neurotoxicity *in-vitro*.



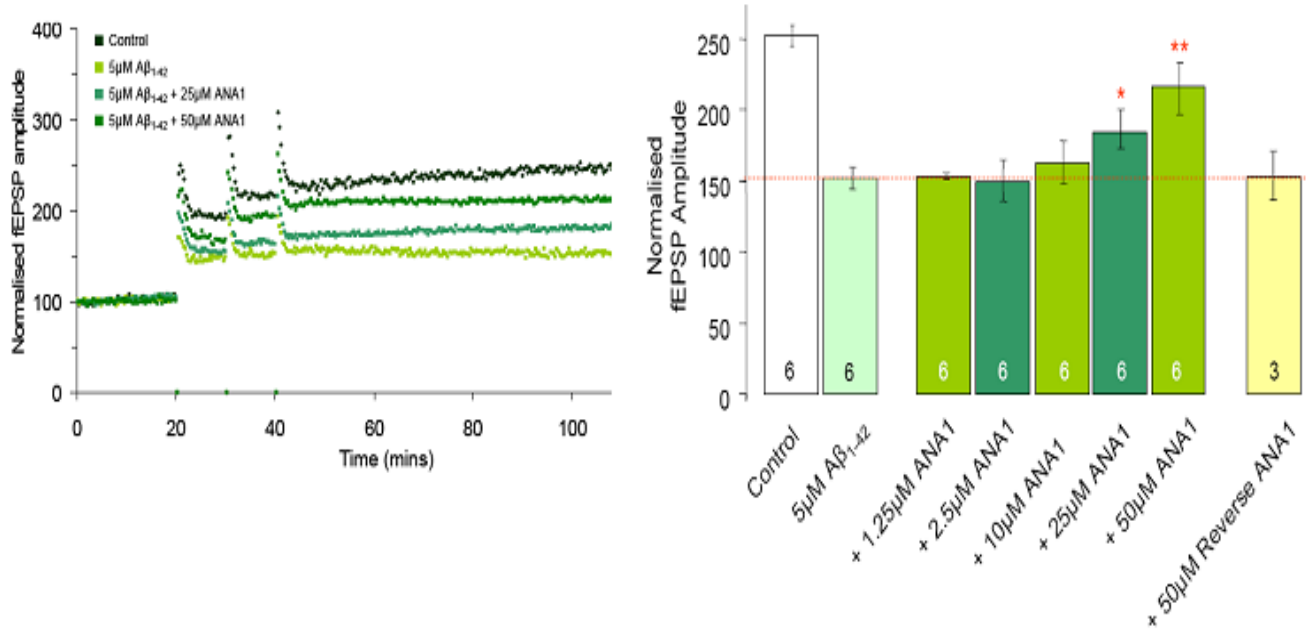
Schematic representations of Alzhyne peptide (green) binding to SOD-like activity site of beta-amyloid.

Preliminary Evidence

Injection of beta-amyloid in rat brains is a commonly used method to assess its neurotoxic effects. Alzhye observed that intracerebral injection of beta-amyloid together with ANA-1 markedly reduced formation of beta-amyloid deposits in the brains of treated animals. These findings indicate ANA-1 facilitates the clearance of beta-amyloid from the brain.

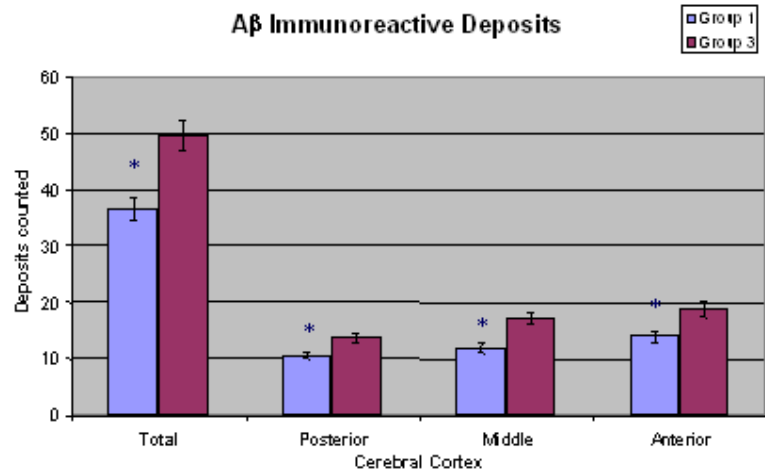
Zebrafish is a predictive animal model for neurotoxicity screening *in-vivo*. Alzhye used zebrafish models to assess whether ANA-1 and ANA-5 prevent beta-amyloid-induced neurotoxicity. The data show both lead peptides significantly inhibited beta-amyloid-induced neurotoxicity in zebrafish embryos.

In neuroscience, long-term potentiation (LTP) is defined as the long-lasting improvement in communication between two neurons achieved by stimulating them simultaneously. Since neurons communicate via chemical synapses, and because memories are believed to be stored within synapses, LTP is generally considered the major cellular mechanism underlying learning and memory. Alzhye examined slice cultures of brain tissue injected with beta-amyloid and treated with its peptides and found that ANA-1 and ANA-5 reversed the depression of LTP memory recordings induced by beta-amyloid dosing.



Effect ANA-1 on beta-amyloid - induced depression of LTP

In a proof of concept study with Dr. Efrat Levy (Nathan Kline Institute, New York), Alzhye demonstrated that ANA-5 reduced amyloid plaque deposits by 27% in a transgenic mouse model of Alzheimer’s disease.

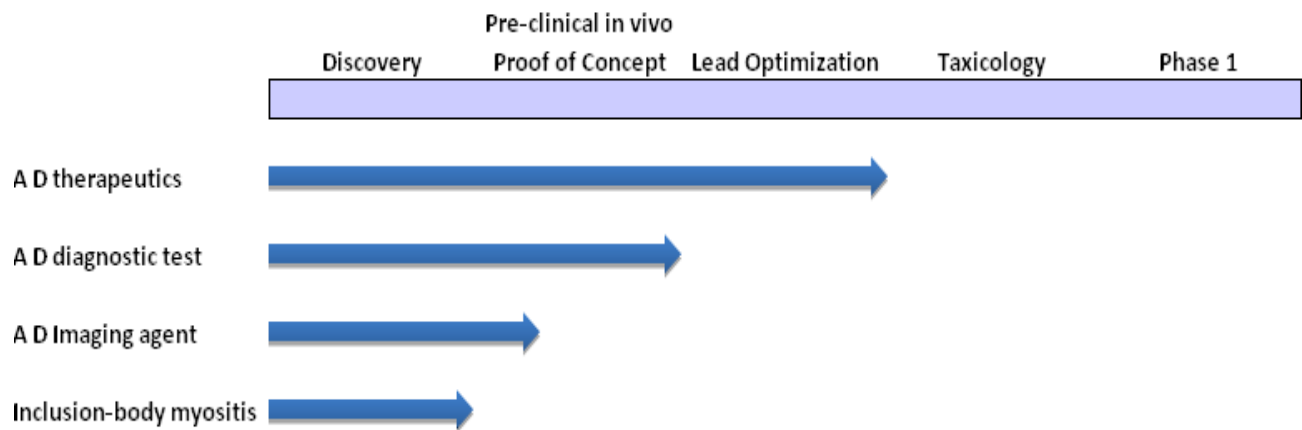


Treatment with ANA-5 (blue bars) reduced brain beta-amyloid deposits in transgenic mouse model of Alzheimer’s disease compared with saline treatment (purple bars).

All of this evidence indicates that ANA-5 may be the first in a new class of therapeutic drugs for the treatment for Alzheimer’s disease. Based on these encouraging pre-clinical results, Alzhyne has opted to advance ANA-5 into clinical development. The Company has undertaken a lead optimization program with Australia’s Commonwealth Scientific and Industrial Research Organization (CSIRO) with the aim of developing an orally available analog of ANA-5 for use in clinical trials.

Because of its neutralizing effect on beta-amyloid, ANA-5 also holds potential as a treatment for another debilitating disease - Inclusion Body Myositis, an age-related disease caused by beta-amyloid toxicity in muscle cells.

Alzhyne Pipeline



Alzhyne has partnered with a U.K.—based biotech firm, Senexis, on the development of a serum-based diagnostic test for early detection of Alzheimer’s disease.

Diagnostic Blood Test

Alzhyne plans to initially focus on the development of a serum-based test that can diagnose Alzheimer’s disease at an early stage. At present, diagnostic methods for Alzheimer’s disease rely on subjective cognitive tests or expensive MRI scans that are not generally introduced until the patient’s dementia symptoms are already apparent. Alzhyne has initiated a research program to develop a blood test of serum-based biomarkers for detecting Alzheimer’s disease.

A diagnostic test would have tremendous commercial value since such a test would facilitate:

- More accurate diagnosis of Alzheimer’s disease at early stages of the illness before significant memory loss occurs;
- Earlier treatment and more appropriate management of Alzheimer’s disease patients;
- Identification of patients with mild cognitive impairment likely to progress to Alzheimer’s disease; and
- Monitoring the response of patients being treated with new beta-amyloid targeting therapeutics.

In 2005, Datamonitor estimated the potential market for a diagnostic test at US\$1.0 billion. Alzhyne believes development of its blood test is potentially achievable as a milestone prior to the Company’s planned 2011/2012 initial public offering.

Blood Test Partnership

In December 2008, Alzhyne announced an agreement with Senexis Ltd (United Kingdom) to collaborate on the development of a diagnostic test for the early detection of Alzheimer’s disease. The goal of the research collaboration is to develop a reliable, low-cost test for detecting Alzheimer’s disease biomarkers in the blood. Senexis is providing peptide-based ligands that Alzhyne can use to assess their binding properties to beta-amyloid.

Imaging Agent

The Company has partnered with the Australian Nuclear Science and Technology Organization (ANSTO) to develop an ANA-5 analog as a radiopharmaceutical agent for imaging beta-amyloid deposits in brain tissue. ANSTO is Australia’s national nuclear research and development organization and the center of Australian nuclear expertise. Its research infrastructure includes Australia’s only nuclear reactor, particle accelerators, radiopharmaceutical production facilities, and a range of other unique research facilities.

Because ANA-5 binds to a specific site within the human beta-amyloid protein, radio-labeling the compound may enable Alzheimer’s disease to be imaged using either Positron Emission Tomography (PET) or Single Photon Emission Computed Tomography (SPECT) techniques.

Development Agreements

As part of its agreement with ANSTO, Alzhyne will work with that organization to jointly investigate and develop ANA-5 as well as other compounds agreed upon by the two parties as radiopharmaceuticals for imaging Alzheimer’s disease. The two entities have agreed to jointly share all rights and interests to inventions, discoveries or improvements, patentable and not patentable, resulting from the work undertaken as part of the research collaboration.

Alzhyne is working with ANSTO to develop ANA-5 as a radiopharmaceutical imaging agent and with CSIRO to identify other lead drug candidates.

The Company is partnering with CSIRO on the identification of lead drug candidates to advance through pre-clinical development and clinical trials. CSIRO is Australia's national scientific agency and among the world's largest research organizations. It ranks in the top 1% of world scientific institutions in 12 of 22 research areas, and participates in over 740 research projects involving scientific organizations in 80 countries.



In early 2009, Alzhyne finalized Pipeline Agreements with Edith Cowan University and the Sir James McCusker Foundation for Alzheimer's Disease Research, Inc., giving the Company first rights of refusal to acquire and commercialize research pertaining to the diagnosis and treatment of Alzheimer's disease.

Management & Board of Directors

The Company's Board and management team have extensive pharmaceutical company experience encompassing all aspects of product development, including research and development, regulatory filings, intellectual property management and commercialization.

William Clough
Independent Chairman (Non-Executive)

William Clough, AO OBE

Mr. Clough is a prominent and highly successful Australian industrialist, entrepreneur and angel investor. He has decades of experience as a business operator and administrator and served on the Senate of the University of Western Australia for 12 years. Mr. Clough is a former Chairman and Director of Clough Limited, the holding company for Clough Engineering Group and has held board positions with several Australian companies. He was awarded the Queen's Silver Jubilee Medal in 1977, Officer of the Order of the British Empire in 1979, Officer of the Order of Australia in 1990 and received an Honorary Degree of Doctor of Engineering from the University of Western Australia in 1990. Mr. Clough's company, McRae Technology Pty Ltd, was the founding investor of Alzhyme.

Dr. Andrew Sierakowski
Independent Director (Non-Executive)

Dr. Andrew Sierakowski

Dr. Sierakowski is the Director of the Office of Industry and Innovation at the University of Western Australia. In addition, he serves as Chairman of Knowledge Commercialization Australia (KCA), a group representing organizations and individuals involved in knowledge transfer. Dr. Sierakowski earned his BSc and PhD at the University of Western Australia and completed Post Doctoral work in the United Kingdom and Switzerland. In 1980, he joined Kodak Australia in Melbourne as Group Leader in Research and Development, where he coordinated large technology transfer and commercialization projects for Kodak worldwide. During his tenure with Kodak, Dr. Sierakowski acquired broad expertise in manufacturing, technical marketing and quality assurance, overseeing projects in Australia, France, Asia and the U.S.

Dr. Terry Bayliss
Independent Director (Non-Executive)

Dr. Terry Bayliss

Dr. Bayliss is a Fellow of the Royal Australasian College of Medical Administrators and has worked as a Medical Registrar at both Royal Perth Hospital and Hollywood Private Hospital. At present, he serves as the Coordinator of Development Projects and Research at Hollywood Private Hospital. From 1994-2001, Dr. Bayliss served as Director of Medical Services at the Hollywood Private Hospital. Since 1999, he has been the President of the Hollywood Private Hospital Research Foundation. He is the current Chairman of the Research Ethics Committee at Hollywood Private Hospital, and a member of the Western Australia Therapeutics Advisory Group and the Western Australia Research Tissue Network Advisory Committee. In addition, Dr. Bayliss serves on the Board of the McCusker Foundation for Alzheimer's Disease Research, Inc., and was the Chairman of the Board in 2005.

Dr. Greg Thomas
Chief Executive Officer

Dr. Greg Thomas

Dr. Thomas brings to the Company over 25 years experience in research and management in both the academic and biotechnology sectors. He has extensive international experience in managing discovery and pre-clinical research development programs and early stage clinical development (Phase

I trials). Dr. Thomas formerly served as Chief Science Manager of Neuren Pharmaceuticals in Auckland, New Zealand. While employed at Neuren, Dr. Thomas gained experience in all aspects of the drug development process, from early discovery through late-stage commercialization. He oversaw an IND (Investigational New Drug) filing for Glyproate®; this product has since progressed to Phase III clinical trials. Dr. Thomas previously worked at Prince Henry's Institute for Medical Research (Melbourne), Medical Research Council Reproductive Biology Unit (Edinburgh), National Institute for Medical Research (London) and Liggins Institute (Auckland).

Professor Ralph Martins
Chief Scientific Officer

Professor Ralph Martins

Professor Martins is the founding scientist and Chief Scientific Officer of Alzhyne. He is an internationally recognized leader in Alzheimer's disease research and leads a team of more than 25 researchers at the Sir James McCusker Alzheimer's Disease Research Unit at Hollywood Private Hospital and Edith Cowan University. Professor Martins trained with Professor Colin Masters in the early 1980s; this group of researchers was the first to successfully identify, isolate and characterize the beta-amyloid protein in senile plaques in the human Alzheimer's brain. Professor Martins was the first to propose and demonstrate that the Alzheimer's brain was under oxidative stress. Since establishing his own research group in Perth in 1990, Professor Martins and his team have continued to work towards unraveling the mysteries of the disease processes and uncovering new therapies for effectively treating Alzheimer's disease. Professor Martins is the Foundation Professor of Ageing and Alzheimer's Disease at Edith Cowan University and the Founding Director of the Centre of Excellence for Alzheimer's Disease Research and Care. He has published over 110 scientific papers and reviews on Alzheimer's disease.

Scientific Review Board

Alzhyne has also established a strong international Scientific Review Board that leverages the strength and expertise of Professor Martins' collaborators and enhances the Company's research efforts. The Scientific Review Board consists of the following individuals:

Professor Sam Gandy – Chair (Thomas Jefferson University)

Dr. Pankaj Mehta – Institute for Basic Research in Development Disabilities, Staten Island, New York

Professor Peter Hudson – Commonwealth Scientific and Industrial Research Organization (CSIRO)

Associate Professor Craig Atwood – Research Director (Wisconsin Alzheimer's Institute, University of Wisconsin)

Professor Paul Fraser – University of Toronto

Dr. Trevor Payne – Ex-Novartis

Market Overview

Multi-Billion Dollar Alzheimer's Treatment Market

Alzheimer's disease is the most common cause of dementia, constituting 60% to 70% of all cases. This disease initially involves parts of the brain that control thought, memory and language. Alzheimer's disease usually begins after age 60 and the risk of the disease increases with age, doubling every five years after age 65. According to the U.S. National Institute on Aging, about 5% of men and women ages 65 to 74 have Alzheimer's disease and nearly half of those age 85 or older may have the disease.

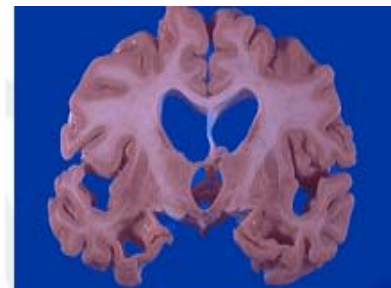
At present, there are no cures or preventatives for Alzheimer's disease. Treatment is limited to a handful of drugs that treat disease symptoms but don't halt underlying neurodegeneration. Sales of symptom-treating drugs exceed US\$2.5 billion annually. The potential market for a cure or preventative could be easily 10 times greater at around US\$25 billion. Alzhyme estimates the potential market for its diagnostic test at US\$1.0 billion.

The global market for drugs that treat Alzheimer's disease symptoms exceeds US\$2.5 billion. The potential market for an Alzheimer's disease cure or vaccine is easily 10 times larger.

In this progressive and ultimately fatal disease, nerve cells in the brain degenerate and die for unknown reasons. Over time, the Alzheimer's-affected brain shrinks dramatically, affecting nearly every brain function. Alzheimer's disease currently affects about 18 million individuals and their families worldwide. Unfortunately, the incidence of the disease is rising as the world's population ages, and the number of Alzheimer's patients is forecast to double by 2025. The scope of the challenge, in terms of both human suffering and economic costs, has encouraged government agencies around the world to subsidize Alzheimer's disease research through grants, subsidies and other financial enticements. The Alzheimer's Association in the U.S. has set a goal of \$1.0 billion in federal funding annually for Alzheimer's disease research, and the Australian government has committed \$320 million over the next five years for dementia research and support.



Normal brain



Alzheimer's brain

Approximately 5.2 million Americans already suffer from Alzheimer's disease and it is estimated that 10 million baby boomers will develop this illness in their lifetime. Alzheimer's disease is already the sixth leading cause of death in the U.S., ahead of diabetes, and a new case is diagnosed every 71 seconds. While Alzheimer's disease is associated with aging, this disease is not considered a normal part of aging.

Alzheimer's disease is named after Dr. Alois Alzheimer, a German physician who in 1906 identified abnormal changes in the brain tissue of a woman who had died of an unusual mental illness. He found abnormal clumps (senile plaques) and tangled bundles of fibers (neurofibrillary

tangles) in her brain. Today, plaques and tangles are considered indicative of Alzheimer's disease.

Scientists have also identified other brain changes in Alzheimer's patients. Nerve cells die in areas of the brain vital to memory and connections between nerve cells are disrupted. Levels of some chemicals known to carry messages between nerve cells decline. By disrupting these messages, Alzheimer's disease impairs thinking and memory.

Age is the best known risk factor for Alzheimer's disease, but researchers believe the disease may have multiple causes and risk factors. Genetics plays a role in one form of the disease. Risk factors associated with heart disease and stroke may also increase Alzheimer's disease risk.

Rather than having one single cause, most researchers think Alzheimer's disease may have multiple causes and a variety of risk factors that impact each person differently. Age is the most important known risk factor; the risk of the disease doubles every five years after age 65. Family history is also a risk factor, with genetics playing an important role in some cases. For example, early onset familial Alzheimer's disease, a rare form of the illness which typically occurs between the ages of 30 and 60, is inherited. The most common form of the disease (late onset Alzheimer's disease), has no obvious inheritance pattern, but several risk factors may interact with each other and with non-genetic factors to cause the disease.

One identified risk factor for late-onset Alzheimer's disease involved a gene that produces apolipoprotein E (ApoE). Everyone has ApoE; this protein helps carry cholesterol in the blood. However, about 15% of the population carries a form of the gene associated with increased risk of Alzheimer's disease. It is likely researchers will identify other genes in the future that increase risk or offer some protection from Alzheimer's disease.

In addition to genetics, scientists are investigating the role education, nutrition and environment play in Alzheimer's disease. The evidence is increasing that certain risk factors associated with heart disease and stroke, such as high blood pressure, high cholesterol, and low levels of folate, may increase Alzheimer's disease risk. There is also a growing body of evidence that remaining physically, mentally and socially active provides some level of protection from the disease.

Alzheimer's Disease Symptoms

Alzheimer's disease begins slowly. Its initial symptoms are generally mild forgetfulness resembling age-related memory change. However, most people with mild forgetfulness do not have Alzheimer's disease. In the early stages of the disease, patients may have difficulty remembering recent events, activities or names of familiar people and places. Simple math problems become more difficult. As the disease progresses, symptoms become increasingly severe and noticeable. For example, patients with moderate-stage Alzheimer's disease may forget how to do simple tasks such as brush their teeth or comb their hair. They may fail to recognize familiar persons and places and/or experience difficulty in speaking, comprehending, reading or writing. In later stages, patients may become anxious or aggressive, wander from home and eventually require round-the-clock care.

Diagnosing Alzheimer's Disease

Early diagnosis of Alzheimer's disease provides the best chance of effectively treating the symptoms. At present, the only definitive way to diagnose Alzheimer's disease is post-mortem, examining brain tissue for plaques and tangles. In living patients, diagnosis is limited to "possible" or "probable." Physicians currently rely on the following methods to diagnose Alzheimer's disease:

- Questions about the patient's general health, past medical issues and ability to carry out daily activities;
- Tests of memory, problem-solving and comprehension;
- Medical tests involving blood, urine and spinal fluid and/or brain scans;

These tests are useful in identifying Alzheimer's disease-like symptoms but cannot differentiate between Alzheimer's disease and other conditions with similar symptoms such as thyroid problems, drug reactions, depression, brain tumors and blood vessel disease.

Treating Symptoms

Alzheimer's disease progresses over a period of several years from mild memory loss to severe brain damage, but the pathological processes of Alzheimer's disease begin years before clinical symptoms are observed. Although the rate of disease progression varies from person to person, on average Alzheimer's patients live for another eight to ten years. Some Alzheimer's patients, however, have been known to live as long as 20 years post-diagnosis.

A few approved drugs offer temporary delays in the worsening of cognitive symptoms but can't stop neurodegeneration and the progression of Alzheimer's disease.

Drugs that treat the symptoms of the disease act by inhibiting acetylcholinesterase, the main enzyme that breaks down acetylcholine. Acetylcholine is a chemical messenger involved in memory, judgment and other thought processes. In about 50% of patients, cholinesterase inhibitors offer modest, albeit temporary delays in the worsening of cognitive symptoms. However, these drugs do not stop underlying degeneration and the disease inevitably progresses. Side-effects associated with cholinesterase inhibitors include nausea, vomiting, loss of appetite and increased frequency of bowel movements. Donepezil (Aricept), rivastigmine (Exelon), and galantamine (Razadyne, previously known as Reminyl) are the drugs most often prescribed for early stage Alzheimer's disease. Tacrine (Cognex), the first cholinesterase inhibitor, was approved in 1993, but is rarely prescribed today because of adverse side-effects, which include possible liver damage. Memantine (Namenda) is approved for the treatment of moderate to severe Alzheimer's disease, but its effects are also limited. Memantine works by regulating the activity of glutamate, a chemical involved in information processing, storage and retrieval. In addition to cholinesterase inhibitors, physicians may prescribe other medications to control Alzheimer's disease behavioral symptoms such as sleeplessness, agitation, anxiety and depression.

NSAID Research

Nonsteroidal anti-inflammatory drugs (NSAIDs) have been studied as a possible treatment for Alzheimer's disease. The underlying theory is that inflammation in the brain contributes to Alzheimer's damage. So far, clinical studies have failed to demonstrate any benefit from NSAID drugs. In clinical studies of rofecoxib (Vioxx) and naproxen (Aleve), neither drug was able to delay the progression of the disease. Clinical trials investigating whether celecoxib (Celebrex) and/or naproxen prevented the development of Alzheimer's disease in healthy seniors were suspended due to concerns about cardiovascular risk.

Antioxidants, Ginkgo Biloba and Estrogen Treatments

Another theory postulated antioxidants may slow the progress of Alzheimer's disease. A clinical study several years ago showed Vitamin E slowed cognitive decline in early-stage Alzheimer's patients by a few months. New studies are investigating whether Vitamins E and C may slow the advance of Alzheimer's disease. Clinical trials involving antioxidants

are ongoing or planned, including studies of Vitamins E and C, alpha-lipoic acid and coenzyme Q in treating patients with mild to moderate Alzheimer's disease.

Anecdotal evidence had suggested that ginkgo biloba eased Alzheimer's disease symptoms, but clinical studies found no evidence that ginkgo biloba could delay cognitive decline or prevent dementia in seniors.

Other studies have suggested that estrogen, often used to treat menopausal symptoms in older women, may protect the brain, and researchers are evaluating the ability of estrogen to reduce Alzheimer's disease risk and/or slow disease progression. So far, clinical studies have failed to show estrogen as effective in slowing the advance of already diagnosed Alzheimer's disease. In fact, one study indicated older women treated with estrogen and progestin had increased risk of dementia, including Alzheimer's disease.

Economic costs associated with care of Alzheimer's patients are estimated at \$150 billion in the U.S. and \$315.4 billion worldwide.

Economic Costs of Alzheimer's Disease

In 2005, the Alzheimer's Association estimated annual U.S. direct and indirect healthcare costs associated with Alzheimer's disease and other forms of dementia at approximately \$150 billion. Global healthcare costs for the world's Alzheimer's patients were estimated at \$315.4 billion. The Alzheimer's Association notes caregiver's burden increases dramatically in the late stages of Alzheimer's disease, when patients cannot maintain independent function and are frequently bedridden.

Other U.S. statistics gathered by the Alzheimer's Association showed:

- Average lifetime costs of caring for an Alzheimer's patient were \$174,000;
- Annual care costs ranged from \$18,400 for someone with mild Alzheimer's disease to \$36,132 for someone with severe symptoms;
- Healthcare costs to businesses were \$24.6 billion;
- 7 of 10 Alzheimer's patients live at home where 75% of the care costs are absorbed by the family. These costs averaged \$19,000 per year;
- Alzheimer's caregivers cost businesses \$36.5 billion, including costs for absent employees;
- Medicare payouts for beneficiaries with Alzheimer's disease were \$91 billion;
- Medicaid expenditures on residential dementia care were \$21 billion.

With the number of Alzheimer's patients and related costs projected to rise dramatically, the need is urgent for new treatments. Speaking to members of the U.S. Senate in 2005, Alzheimer's Association President Sheldon Goldberg urged Congress to increase federal investment in Alzheimer's research. He noted that, Medicare beneficiaries with Alzheimer's disease presently account for 34% of Medicare spending, even though they constitute only 12.8% of the senior population. With America's 77 million baby boomers soon joining the high risk age group, the number of Americans with the disease will increase exponentially. Adequate funding for research must begin now before baby boomers reach the age where risk of the disease becomes highest.

According to Goldberg, every dollar spent today on research would produce tremendous savings for taxpayers in the form of reduced Medicare and

Medicaid costs – returns of 12-to-1 by 2015, 30-to-1 by 2025 and over 100-to-1 by 2050. Substantial cost savings may also be achieved by delaying the disease's onset or slowing its progression. A preventative or cure would produce exponentially higher returns.

Competition

Research Trends

Researchers are confident new treatment options for Alzheimer's disease will become available over the next ten years that not only offer symptom relief but also halt or reverse disease progression. While some may view this belief as overly optimistic, there is general agreement that Alzheimer's research has progressed by leaps and bounds in recent years. A powerful growth driver for research and development is the reality that new drugs offering even slight improvement over existing drugs would be welcome, given the severity of the disease and its growing incidence. The medical community's keen interest in new Alzheimer's drugs is evidenced by Aricept's success. This drug offers relatively modest benefits but is nevertheless widely prescribed.

Alzheimer's disease research is entering a critical stage, with several late-stage drugs in development that hold considerable promise but lack clinical data.

Alzheimer's disease research is entering a critical phase with several late-stage compounds in development that hold considerable promise but lack clinical trial data. Many of these drug candidates target beta-amyloid, the protein that forms senile plaques. Other research approaches focus on altering cholesterol and glucose metabolism, modifying tau (a protein found in neurofibrillary tangles) or developing neuroprotectives. The improved understanding of Alzheimer's disease resulting from various research approaches increases the likelihood that disease-modifying agents will be perfected in the near future.

A diagnostic test for detecting Alzheimer's disease in its early stages may become available within five years. By identifying patients who would otherwise remain undiagnosed during early disease stages, a diagnostic test will expand the overall Alzheimer's disease treatment market. In addition, improved diagnostics assist research programs by allowing better monitoring of patient response to drug candidates.

Biotech Collaborations

Central nervous system disorders have traditionally been the realm of big pharmaceutical companies. However, biotech innovations, including the use of monoclonal antibodies, have taken a lead role in Alzheimer's disease research. Recent multi-million dollar technology acquisitions and licensing agreements evidence the high value pharmaceutical companies attach to biotech research in Alzheimer's disease.

Pfizer agreed to cash and future milestone payments totaling \$725 million for Dimebon, Medivation's development-stage Alzheimer's disease drug.

Pfizer (NYSE:PFE) acquired San Francisco-based Rinat Neuroscience mainly to obtain Rinat's anti-beta-amyloid antibody. While financial terms of the 2007 acquisition were not disclosed, analysts put the purchase price at approximately US\$300 million. Genetech (NYSE:DNA) formed a research collaboration with AC Immune last year to develop anti-beta-amyloid antibodies for the treatment of Alzheimer's disease. According to AC Immune's CEO, Genetech was one of several prominent suitors for its technology. Novartis (NYSE:NVS) acquired immunotherapy expertise through its research collaboration with Switzerland-based Cytos, and the two companies are jointly developing a new therapeutic agent, CAD106.

In September 2008, Pfizer signed an agreement with Medivation (NASDAQ:MDVN) to co-develop and market Dimebon, an investigational new drug for the treatment of Alzheimer's disease. Dimebon works by improving the function of mitochondria - energy generators in cells that play a central role in governing brain cell health and overall function. Under the terms of the agreement, Medivation received upfront cash payments of US\$225 million, becomes eligible for milestone payments of up to US\$500

million and potentially qualifies for additional, undisclosed commercial milestone payments.

Beta-Amyloid Aggregation Inhibitors

These compounds prevent beta-amyloid aggregation and the formation of senile plaque. Disaggregation of plaques may also allow injured nerve cells to undergo self-mediated repair. Potential disadvantages of beta-amyloid aggregation inhibitors include increased levels of more toxic, soluble forms of beta amyloid when plaques and fibrils are broken down. In addition, agents that prevent oligomerisation also act on regions of beta amyloid not involved in the production of free radicals.

Neurochem (NASDAQ:NRMX) was involved in Phase III clinical trials of a beta-amyloid aggregation inhibitor, Alzhemed, but halted clinical trials due to disappointing results. Neurochem now plans to market Alzhemed as a dietary supplement rather than a drug.

Active and Passive Immunotherapies

Immunotherapy is one of the principal approaches being used to target beta-amyloid. Vaccines and antibodies reduce Alzheimer's disease effects through manipulation of the patient's immune system. Problems with these vaccines became apparent in clinical trials when some patients developed severe brain inflammation. Another challenge is that immune response and antibody production diminish with the aging process, and some immune systems may not be able to produce sufficient antibodies to generate therapeutic effects.

Several companies, including Novartis, Cytos, AC Immune and Affiris, are working on vaccines that stimulate the body's immune system. Wyeth/Elan, Genetech and Pfizer are taking a different tact by developing anti-beta-amyloid antibodies that clear this protein from the brain through passive immunization.

Early on, Wyeth (NYSE:WYE) and Elan (NYSE:ELN) collaborated on an active beta-amyloid vaccine, AN-1792. The clinical product consisted of a synthetic form of beta amyloid, administrated with an adjuvant to elicit an immune response. Clinical results showed patients treated with AN-1792 were less likely to experience deterioration in cognitive tests, and autopsy results revealed plaque reduction in some patients. In addition, the level of tau protein declined in some patients, suggesting a reduction in degenerating neurons. Problems with the drug's safety profile quickly became obvious, however, and trials of AN-1792 were suspended in 2002 when some patients developed encephalitis. Wyeth and Elan are currently collaborating on a new product based on a truncated version of the vaccine and recruiting for clinical trials.

Wyeth and Elan are also collaborating on the development of bapineuzumab, a humanized monoclonal antibody that induces passive immunization. It delivers anti-beta-amyloid antibodies directly to the patient, rather than requiring the patient to mount his own immune system response. Bapineuzumab produced disappointing results in Phase II trials last year by failing to achieve its clinical endpoints for cognition. The high dose group in the trial also showed vasogenic edema. However, a low dose Phase III trial is currently underway, which commenced before efficacy of the Phase II trial was established.

Other pharmaceutical companies with anti-beta-amyloid antibodies in development include Pfizer, with its RN 1219 product obtained from Rinat,

and Eli Lilly (NYSE:LLY) with two monoclonal antibody products in clinical trials. Pfizer modified Rinat's antibody so that it does not bind to complement, which they believe reduces risk of inflammation. Pfizer's RN 1219 product is currently in Phase I clinical trials.

Gamma-Secretase Inhibitors/Modulators

Secretase inhibitors work by inhibiting the activity of beta and gamma secretases, which reduces beta-amyloid production. However, secretase drugs are not target-specific and other metabolic processes in the brain are also affected. As a result, the potential for adverse side-effects is high. Another concern is that secretase drugs only benefit patients with early stage disease; these drugs have no effect on pre-formed plaques. Also, since beta-amyloid load is already high in Alzheimer's patients, these drugs may only minimally impact existing symptoms.

Lilly is enrolling patients for clinical trials of its gamma secretase inhibitor, LY 450139. Last year, Myriad Genetics (NASDAQ:MYGN) reported disappointing results for its gamma-secretase inhibitor, Flurizan, in Phase III clinical trials. Flurizan failed to demonstrate statistically significant results for either of the trial's primary endpoints – cognition and activities of daily living. Myriad has opted to discontinue Flurizan's development.

RAGE Receptor Modulators

Another possible target for Alzheimer's disease research is the Receptor for Advanced Glycation End-products (RAGE). The RAGE receptor belongs to the immunoglobulin super family of cell surface molecules, which have ligands associated with different diseases. RAGE ligands are associated with beta-amyloid fibrils and Alzheimer's disease. Research in this area focuses on biological mechanisms for stopping beta-amyloid accumulation via modulation of a signal transduction pathway.

Pfizer licensed a portfolio of RAGE modulators from Trantech Pharma, agreeing to pay upfront and near-term milestone payments totaling US\$155 million and additional future milestone and royalty payments if RAGE modulators can be commercialized for multiple indications. Pfizer has also agreed to provide US\$18 million to fund further research and expansion of the RAGE portfolio. Transtech's orally available lead compound, TTP 488, is in Phase II clinical trials as a treatment of Alzheimer's disease.

Luteinizing Hormone Reducers

Privately-held Voyager Pharmaceutical believes many diseases of aging may be due to hormone changes associated with the aging process. It theorizes reducing the amount of luteinizing hormone released by the pituitary gland may slow the progression of Alzheimer's disease. Voyager's lead drug candidate, VP 4896, is a biodegradable implant made from leuprolide acetate (already used to treat prostate cancer) and a polymer. Phase II studies are underway evaluating the ability of VP 4896 to stabilize cognitive and functional decline in women with mild to moderate Alzheimer's disease.

Metabolic Process Management

Privately-funded Accera is developing agents that manage metabolic defects and imbalances associated with Alzheimer's disease. Numerous studies have confirmed a sharp drop in glucose uptake in certain areas of the brain begins 10 to 20 years before Alzheimer's disease symptoms appear. Accera believes addressing this metabolic deficiency may reduce the effects of Alzheimer's disease. Accera plans to market a medical food product,

Pfizer has also agreed to upfront and near-term milestone payments totaling \$155 million for Transtech's portfolio of development-stage compounds.

Axona, for dietary management of metabolic processes associated with mild to moderate Alzheimer's disease.

Neuroprotectors

Neuroprotectors strengthen nerve cells against the effects of oxidative stress. In theory, Alzheimer's disease symptoms decline because nerve cells become more capable of withstanding stresses. Neuroprotectors cannot reduce toxic beta-amyloid or stop the formation of fibrils and plaques. While disease effects may be reduced, the core problem of beta-amyloid accumulation remains.

Denmark-based ENKAM Pharmaceuticals is developing a synthetic peptide, FGL, which it believes can stop brain cells from dying and restore the functionality of already affected brain cells. FGL is a neural cell adhesion molecule; it promotes connectivity between cells and the formation of new neurons. ENKAM believes FGL may have therapeutic applications beyond Alzheimer's disease, including its use as an anti-depressant.

Privately-held Ceregene is developing a gene therapy product that delivers nerve growth factor (NGF) to protect and restore damaged neurons. The company was awarded a \$5.4 million NIH grant for its research program and plans to commence clinical trials of its product in 2009.

Chelating Agents

Prana Biotechnology is developing drugs that interfere with the interaction between beta-amyloid and copper and zinc in the brain. These agents address the cause of Alzheimer's disease by neutralizing beta-amyloid before it becomes toxic. While efficacious in neutralizing beta-amyloid, Prana's chelating agents are non-specific, acting indiscriminately on other important brain enzymes that bind metal ions.

In February 2008, Prana announced clinical results for its lead chelating agent, PBT2, which the company characterized as successful. The market responded favorably and Prana's share price jumped more than 40%. Prana recently confirmed plans to enter larger clinical trials of PBT2 and indicated it was seeking an industry partner and licensing agreement.

Cognitive Impairment Treatments

There are also a number of companies developing drugs that treat cognitive impairment. These products address underlying symptoms but are not a cure for Alzheimer's disease.

Memory Pharmaceuticals (NASDAQ:MEMY) reported favorable results from early clinical trials of R4996/MEM63908, a drug being co-developed with Swiss pharmaceutical company Roche. This product acts on the nicotine alpha-7 receptor, which may have utility in improving cognitive function. Roche recently agreed to acquire Memory for US\$50 million. Cortex Pharmaceuticals (NYSE:COR) is developing AMPAKINE compounds that target the AMPA-glutamate receptor complex and amplify the effect of glutamate at the synapse to stimulate brain circuits. Neuro-Hitech is investigating Huperzine, a plant-derived product already being marketed in China as a treatment for Alzheimer's disease.

Prana Biotechnology's share price jumped 40% when favorable results from clinical trials of lead drug candidate, PBT2, were announced.

Milestones

In the last 12-24 months, Alzhyme has improved the protection of its intellectual property, advanced its lead drug candidate through pre-clinical and proof of concept studies, established research collaborations for its therapeutics, imaging agent and diagnostic test, and sought additional funding for its research program.

Alzhyme has established ANA-5, as its lead drug candidate, demonstrated its toxicity prevention capabilities in proof of concept studies and reduced amyloid plaque load 27% in mouse models of Alzheimer’s disease.

Research and Development

Alzhyme’s recent research and development accomplishments include:

- Identifying ANA-5 as its lead drug candidate for the treatment of Alzheimer’s disease;
- Establishing through proof of concept studies that ANA-5 prevents beta-amyloid toxicity, using various *in-vitro* and *in-vivo* models of Alzheimer’s disease;
- Proving that ANA-5 significantly reduced beta-amyloid plaque load in transgenic mouse models of Alzheimer’s disease;
- Improving the sensitivity of its beta-amyloid assay 10-fold.

New research collaboration

In December 2008, Alzhyme announced a collaborative agreement with Senexis for the discovery and development of an Alzheimer’s disease diagnostic test. The collaboration exploits the two companies’ combined resources and intellectual property to accelerate discovery of a reliable, low cost test that detects Alzheimer’s disease at an early stage. At present, there is no effective diagnostic test available.

Intellectual Property

Alzhyme protects its technologies through a combination of patents, patent applications and trade secrets. When the Company was spun off from the University of Western Australia in December 2002, all intellectual property was wholly assigned without encumbrance to the new corporate entity.

In August 2007, Alzhyme obtained an Australian patent covering ‘Screening Methods and the Use of Agents in Identifying the Same.’ The Company has patent applications pending in the United States and Europe, and an international patent application filed for ‘Improved Peptide Composition.’

Territory	Patent number	Status
United States	10/674,456	Under examination
Europe	02787209.2	Under examination
Australia	2002351880	Granted
United States	11/925,279	Divisional application
Territory	Patent number	Status
Australia	2007001767	International Patent Application

Separate Pipeline Agreements with Edith Cowan University and the McCusker Foundation for Alzheimer’s Disease Research, Inc., were finalized in early 2009. These agreements give Alzhyme right of first refusal to commercialize new intellectual property in the areas of treatment and diagnosis of Alzheimer’s disease.

Investment Risks

Development-stage products not approved for commercial sale

The Company's products are in early research and development. There is no guarantee that Alzhyne will be able to successfully develop and commercialize its products. In addition, Alzhyne has no product sales and may be several years away from generating product revenues. The Company's products will require extensive additional research and development, including expensive pre-clinical and clinical testing and regulatory filings, prior to commercialization. There are many reasons why initially promising products fail to be successfully commercialized. For example, clinical trials may be suspended due to safety or efficacy reasons. Even if research and development efforts are successful, there is no guarantee that Alzhyne's products will obtain regulatory approval or can be manufactured in commercial quantities at reasonable costs.

Intellectual Property

Securing patents is integral to tapping the value of discoveries made through pharmaceutical and biotechnology research and development. The granting of a patent, however, does not guarantee that the rights of others are not infringed or that competitors won't develop similar products that may circumvent Alzhyne's patents. The intellectual property rights on which Alzhyne relies to protect its technology may not be adequate, which could enable third parties to use the Company's technology or a similar technology and reduce Alzhyne's competitive advantage. There is no guarantee that the Company's patents will afford meaningful protection. Others may challenge the Company's patents or patents of its licensors. As a result, Alzhyne's patents could be narrowed, invalidated or rendered unenforceable. In addition, there is no guarantee that current and future patent applications will result in patents being issued in Australia, the U.S. or Europe.

Cost of research and clinical trials

Pre-clinical research and clinical trials are very costly and time-consuming, especially for larger Phase III clinical trials. The results of pre-clinical or early-stage clinical trials are not necessarily predictive of safety or efficacy, and later-stage clinical trials may fail to show desired safety and efficacy. The Company and/or regulatory authorities may suspend or terminate clinical trials at any time. There is no guarantee that adequate numbers of patients can be recruited for clinical trials. Other unforeseen developments could prevent or delay completion of clinical trials or increase the Company's costs.

Funding risk

Alzhyne will require significant additional funding to advance its research programs. The Company may seek to raise capital through stock offerings, loans or entering into collaborative agreements. Issuing equity dilutes the interests of existing shareholders while debt financing often contains restrictive covenants.

Dependence on third-party collaborators

The Company plans to pursue collaborative arrangements with pharmaceutical industry partners. Third party collaborators may be asked assist with funding, clinical trials, manufacturing, regulatory approvals and product marketing. If the Company can't find a partner, Alzhyne may be required to develop and commercialize products at its own expense. Self-funding would likely limit the number of product candidates and strain the Company's internal resources.

Clinical trials are very expensive and time-consuming. Alzhyne will require additional funding to advance its research programs and will likely seek a partner interested in licensing its technology.

Product Liability and Uninsured Risks

Alzyme is exposed to potential product liability risks inherent in the research and development, manufacturing, marketing and use of its products and products developed through collaborative partnerships. The Company plans to purchase insurance to help manage these risks; however, there is no guarantee Alzyme will be able to obtain insurance on reasonable terms. The Company's insurance may be insufficient to cover large claims or the insurer may refuse coverage on some claims.

There is a risk that the Company's products may contain unknown defects, which could result in loss of revenues and market share, diversion of resources to correct the problem, damage to Alzyme's reputation, and increased insurance costs and law suits.

Operating losses and negative cash flow

The Company expects to incur operating losses for at least the next several years due to the costs of research programs, clinical trials, manufacturing activities and to a lesser extent, general and administrative expenses. There is no guarantee that the Company can successfully develop, manufacture and commercialize any product, or achieve positive cash flow and profitability.

Summary

Alzhyme is developing diagnostic tests, imaging agents and therapeutics for the treatment of Alzheimer's disease. The Company has identified a family of peptides that selectively neutralize beta-amyloid, a naturally occurring protein whose overproduction and accumulation in the brain is associated with Alzheimer's disease. Alzhyme's novel approach has major advantages over other existing drugs and drug candidates since its compounds selectively neutralize beta-amyloid-induced neurotoxicity without interfering with other metabolic processes. Several competitor drug candidates also neutralize beta-amyloid toxicity but trigger undesirable side-effects because other brain enzymes are also affected. Alzhyme has identified a family of 25 peptides that specifically target beta-amyloid and is developing orally available analogs that mimic their action.

In zebrafish models, Alzhyme's lead drug candidate ANA-5 has shown the ability to significantly inhibit beta-amyloid-induced neurotoxicity. Later proof of concept studies demonstrated that treatment with ANA-5 reduced amyloid plaque deposits 27% in a transgenic mouse model of Alzheimer's disease. Based on these very encouraging pre-clinical results, Alzhyme has opted to further develop ANA-5 as the first in a new class of therapeutics for the treatment of Alzheimer's disease.

Alzhyme has a broad product pipeline, numerous research collaborations, an internationally recognized research team and solid prospects for technology licensing agreements in the near future.

Alzheimer's disease is a huge market with unmet medical needs. This disease is already the sixth leading cause of death in the U.S., with a new case diagnosed every 71 seconds. An estimated 18 million individuals and their families worldwide are affected by Alzheimer's disease. Over a period of several years, the disease causes memory loss, loss of cognitive function and eventually death. The Alzheimer's brain shrinks dramatically until virtually every brain function is affected. The incidence of Alzheimer's disease is projected to double by 2025 due to the world's aging population. Despite social and economic costs of Alzheimer's disease, estimated at hundreds of billions of dollars each year, there is at present no vaccine and no cure. Treatment options are limited to a few drugs that temporarily relieve symptoms. Global sales of symptom-treating drugs are estimated at US\$2.5 billion and industry analysts believe the sales potential of a disease preventative and/or cure could be in a US\$25 billion range.

Most researchers believe a single magic bullet cure for Alzheimer's disease is unlikely, given the multi-factorial nature of the disease, allowing for some overlap. Products approaching the condition from different endpoints may prove complementary, creating room for a variety of different drugs and treatments in this marketplace.

With the goals of minimizing risk and enhancing near-term revenue prospects, Alzhyme is pursuing an integrated pipeline approach by developing diagnostic tests, imaging agents and novel therapeutics for Alzheimer's disease. The potential value of the Company's pipeline is validated by research agreements with academic, government and corporate partners. Senexis is collaborating with Alzhyme on the development of a serum-based test, ANSTO is helping the Company develop imaging agents and CSIRO is working with Alzhyme to develop lead drug candidates. Pipeline agreements with Edith Cowan University and the Sir James McCusker Foundation for Alzheimer's Disease Research, Inc., give Alzhyme rights of first refusal to commercialize discoveries made through

joint research.

Over the next 12 to 24 months, Alzhyme expects to:

- Complete development of a diagnostic blood test for the early detection of Alzheimer's disease;
- Establish clinical relevance and validation of a beta-amyloid blood assay in an Alzheimer's patient population;
- Complete lead optimization for ANA-5;
- Begin proof of concept transgenic animal studies of an oral analog of ANA-5; and
- Complete and publish results of a beta-amyloid PET imaging study using a radio-labeled analog of ANA-5 as the molecular imaging agent.

The Company believes development of a serum-based diagnostic test may be achievable as a milestone prior to 2011/2012.

Alzhyme's research efforts are led by Professor Ralph Martins, an internationally recognized leader in Alzheimer's disease research. Professor Martins was the first to propose and demonstrate the Alzheimer's brain is under oxidative stress. His discovery has become the focal point of global research into new treatments for Alzheimer's disease. Through Professor Martins' relationships with Edith Cowan University, the McCusker Foundation, government agencies, international research groups and care providers, Alzhyme gains access to leading-edge research facilities and related infrastructure.

Alzheimer plans to advance its products through pre-clinical and early clinical development, then pursue licensing agreements with pharmaceutical industry partners for clinical trials, regulatory filings and commercialization. Although its products are still relatively early-stage, Alzhyme's pipeline may already have considerable monetary value. This may be inferred from prices recently paid for other Alzheimer's disease drug candidates. For example, Pfizer agreed to pay cash of US\$225 million and milestone payments of US\$500 million for Medivation's development-stage Alzheimer's disease treatment. Rinat Neuroscience's development-stage Alzheimer's disease vaccine was acquired for approximately US\$300 million and Pfizer has agreed to upfront and milestone payments totaling US\$155 million for Transtech's portfolio of drug candidates. Another major pharmaceutical manufacturer Roche recently agreed to pay \$50 million for Memory Pharmaceutical and its drug candidate for treating cognitive impairment.

The investment community is also showing strong interest in Alzheimer's disease research and new research developments. For example, Prana Biotechnology's market value increased by \$50 million following the announcement of positive clinical trial results for its Alzheimer's drug candidate, PBT2. Given the advantages of the Company's technology, which include specific targeting of soluble beta-amyloid and reduced side-effects, we think Alzhyme will be attractive to potential industry partners. Alzhyme plans to monetize the value of its product pipeline through licensing agreements and a future initial public offering.

Income Statement

Income Statement					
For the Fiscal Period Ending Currency	12 months Jun-30-2005 AUD	12 months Jun-30-2006 AUD	12 months Jun-30-2007 AUD	12 months Jun-30-2008 AUD	6 months July - Dec-31-2008 AUD
Revenue	272.0	3,362.0	2,749.0	2,813.0	6,378.0
Other Revenue	-	-	-	-	-
Total Revenue	272.0	3,362.0	2,749.0	2,813.0	6,378.0
Cost Of Goods Sold	-	-	-	-	-
Gross Profit	272.0	3,362.0	2,749.0	2,813.0	6,378.0
Selling General & Admin Exp.	28,034.0	52,380.0	66,176.0	37,425.0	116,361.0
R & D Exp.	22,264.0	139,854.0	39,115.0	8,626.0	1,565.0
Consultant Fees	4,000.0	41,710.0	-	7,000.0	21,000.0
Employee Expense	15,558.0	76,505.0	152,791.0	152,708.0	76,381.0
Operating Income	(69,584.0)	(307,087.0)	(255,333.0)	(202,946.0)	(208,929.0)
Income Tax Expense	-	-	120,931.0	44,250.0	-
Net Income	<u>(69,584.0)</u>	<u>(307,087.0)</u>	<u>(134,402.0)</u>	<u>(158,696.0)</u>	<u>(208,929.0)</u>
Per Share Items					
Basic EPS	(0.029)	(0.096)	(0.04)	(0.043)	(0.006)
Weighted Avg. Basic Shares Out.	2,387,895.0	3,207,827.0	3,322,827.0	3,722,827.0	35,982,616.0
Diluted EPS	(0.023)	(0.08)	(0.034)	(0.037)	(0.005)
Weighted Avg. Diluted Shares Out.	2,969,895.0	3,817,057.0	3,932,057.0	4,332,057.0	40,856,456.0
Dividends per Share	NA	NA	NA	NA	NA
Supplemental Operating Expense Items					
Advertising Exp.	NA	NA	NA	NA	NA
Selling and Marketing Exp.	NA	NA	NA	NA	NA
General and Administrative Exp.	28,034.0	52,380.0	66,176.0	37,425.0	28,034.0
R&D Exp.	22,264.0	139,854.0	39,115.0	8,636.0	22,264.0
Currency	AUD	AUD	AUD	AUD	AUD

Balance Sheet

Balance Sheet					
Balance Sheet as of:	12 months Jun-30-2005	12 months Jun-30-2006	12 months Jun-30-2007	12 months Jun-30-2008	6 months July - Dec-31- 2008
Currency	AUD	AUD	AUD	AUD	AUD
ASSETS					
Cash And Equivalents	129,287.0	97,179.0	57,720.0	22,437.0	30,575.0
Total Cash & ST Investments	129,287.0	97,179.0	57,720.0	22,437.0	30,575.0
Accounts Receivable	2,410.0	9,186.0	55,948.0	47,846.0	-
Total Receivables	2,410.0	9,186.0	55,948.0	47,846.0	-
Inventory	-	-	-	-	-
Prepaid Exp.	-	-	-	608.0	608.0
Other Current Assets	-	-	-	-	-
Total Current Assets	131,697.0	106,365.0	113,668.0	70,891.0	31,183.0
Property, Plant & Equipment	675.0	2,865.0	15,372.0	15,505.0	13,507.0
Other Intangibles	9,028.0	9,028.0	-	52,822.0	52,822.0
Total Non Current Assets	9,703.0	11,893.0	15,732.0	68,327.0	66,329.0
Total Assets	<u>141,400.0</u>	<u>118,258.0</u>	<u>129,400.0</u>	<u>139,218.0</u>	<u>97,512.0</u>
Liabilities					
Accounts Payable	60.0	4,290.0	3,835.0	12,359.0	8,901.0
Total Current Liabilities	60.0	4,290.0	3,835.0	12,359.0	8,901.0
Other Non-Current Liabilities	-	-	100,000.0	100,000.0	100,000.0
Total Liabilities	60.0	4,290.0	103,835.0	112,359.0	108,901.0
Net Assets	141,340.0	113,968.0	25,565.0	26,859.0	(11,389.0)
Equity					
Contributed Equity	604,000.0	883,716.0	929,715.0	1,089,716.0	1,209,716.0
Accumulated Losses	(462,660.0)	(769,748.0)	(904,150.0)	(1,062,856.0)	(1,062,856.0)
Total Equity	<u>141,340.0</u>	<u>113,968.0</u>	<u>25,565.0</u>	<u>26,859.0</u>	<u>146,860.0</u>
Currency	AUD	AUD	AUD	AUD	AUD

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