



**ANNUAL GENERAL MEETING**  
**CHAIRMAN AND CHIEF EXECUTIVE OFFICER'S ADDRESS**  
**MONDAY 31 OCTOBER, 2011**

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Ladies and gentlemen, welcome to the Agenix annual general meeting for 2011.

Thank you for your continued interest and support and for taking the time to come here today.

**Overview of 2011 Financial Year**

Following the considerable challenges of the 2008 and 2009 fiscal years, it is pleasing to report that current assets at 30 June 2011 were \$1.9 million reflecting the successful recovery from SHRG/YSY in Shanghai.

During the 12 months to 30 June 2011, the Group reduced its total liabilities \$2.9 million at the end of FY2010 to \$850,000 as at 30 June 2011. The reduction in liabilities of \$2.1 million arose from \$1,000,000 of convertible notes being converted to equity – an expression of confidence in the company - with the balance of \$1.1 million being legacy debts inherited by this board which we acquitted from cash resources.

Total income for the year ended 30 June 2011 was \$220,000 up from \$53,000 in the previous financial year due to the receipt of interest totalling \$154,000 in respect of the China settlement.

Our focus is on the future and, at the same time, controlling the company's cash resources while deploying them prudently.



## **First quarter of the 2012 Financial Year**

During the quarter just gone, the Company's operational expenditure was approximately \$144,000 per month. This includes salaries and research and development costs expensed as well as activity in support of our business development milestones.

We finished the quarter with \$1.2 million in cash, compared to \$549,000 for the same period in 2010. While our position is solid and our costs remain under tight control, further capital will be required as we move towards the commencement of human clinical trials for AGX-1009 in China in 2012.

Operating activities used cash of \$616,000 including legacy costs of \$40,000. As noted previously, our ongoing administration overheads have been significantly reduced and were down to \$428,000 for the quarter. Like many Australian companies with a global focus, the strength of our dollar continues to reduce the Australian dollar value of funds required by our China subsidiary.

As I just mentioned, Agenix will continue to invest in the scale-up of its China operations as the start of the first human clinical study for AGX-1009 draws closer.

However, even Apple, which executed one of the most remarkable rebirths ever beginning with the iPod, had to go through a decade of pain to get there.

Your board is equal to the challenge of working to build a great business as quickly as we can by providing tremendous products wherever they are needed.

## **Agenix is on track to create long term value for shareholders**

Agenix today is on track to create significant value for shareholders building on the significant achievements to date.

Our lead drug candidate, AGX-1009, targets a large unmet need for next-generation Hepatitis B therapies in China with a competitive product.

Our lead diagnostic, ThromboView®, is a safe and effective diagnostic for pulmonary embolism and deep vein thrombosis.

We aim to build a pipeline of projects targeting China and global markets.



We have achieved a complete transformation of the company based on human and intellectual capital and by partnering our capital with China infrastructure and technical skills.

We are driving the business by reference to technical, clinical and commercial value inflection points and realistic milestones.

We aim for nothing more than and nothing less than competent execution of basics like good corporate governance which I shall come to in a moment, mitigating risk and communicating milestones and results.

We have a networked and commercial approach to achieving term shareholder value by commercialising, as fast as we are able to, next generation drugs and diagnostics with a major focus on opportunities in China.

We do not employ a large internal bureaucracy – our approach is to engage with partners and collaborators from research laboratories to manufacturing.

Currently we have two lead programs working to achieve two genuine value inflection points for investors: the first is a partnering or sale event for ThromboView®. The other is the Clinical Trial Application (CTA) filing for AGX-1009 with China's State Food & Drug Administration in 2012. I shall come to these in a moment.

### **Our business in China is on solid foundations**

Looking at a snapshot of our shareholders and capital, we recovered \$3.6 million from China, undertook a reasonably successful rights issue and negotiated the acquisition of AGX – 1009, a drug candidate supported by the Chinese Government's State Special Funds for Important Newly-Developed Drugs.

The recovery and placement revenues transformed the Company's financial position and are direct evidence of Agenix's proven ability to do business in China.

We believe the value of AGX-1009 has not yet been priced in to our stock by the market.

For those of you who have been long term shareholders, you would know that the Company has a proud history of taking bench-top research through to commercial success in global markets. Since 1987, Agenix has taken over 20 animal and human products across four technology platforms to successful commercialisation then strategic sale and exit.



The Company has even achieved State Food & Drug Administration (SFDA) regulatory approval for a hepatitis B drug in China before exiting the corporate issues that attended that therapy. Agenix still has the people, relationships and methodologies to continue its overall track record of success.

### **Lead drug AGX-1009 aims to help meet large unmet medical needs in China**

Agenix has been involved with the hepatitis B market in China since 2005. China has the largest number of hepatitis B patients in the world, with an estimated 120 million people carrying the surface antigen (HBsAg). An estimated, 20 million people in China suffer from chronic hepatitis B, and 300,000 people die from the disease or its complications every year.

In 2009 it was estimated that the market for hepatitis B treatments in China (excluding Hong Kong, Macao and Taiwan) was \$227.4 million in hospitals alone and \$460 million across the whole market, with an annual growth rate of 31 per cent between 2008 and 2009, and a compound annual growth rate of 56 per cent between 2006 and 2009.

The Chinese hepatitis B drugs market grew by 31 per cent by volume between 2008 and 2009, with a 2006 – 2009 compound annual growth rate of 47 per cent.

The highest selling drug in China for hepatitis B was 'Adefovir' with sales of \$109 million, although other drugs ' Lamivudine' and 'Entecavir' had sales of greater than \$84 million.

Due to improved access to medication and a burgeoning middle class, Datamonitor forecasts that the hepatitis B drugs market in China will reach a total value of \$701.5 million in 2019 in hospitals alone. IMS Health puts the overall market figure at \$1.3 billion. It is a huge market and Agenix is familiar with how it works.

AGX-1009 is a patented tenofovir 'prodrug' with the same active compound as Gilead's FDA-approved tenofovir 'prodrug' Viread. It has the same active ingredient, tenofovir, but contains a different molecular sidechain that drops away as the drug nears its site of desired activity in the body.

Within the area of liver disease, Gilead's Viread is now the most-prescribed treatment for chronic hepatitis B in the US and Europe after receiving regulatory approval in 2008 in those geographies.



We expect this is likely to play out the same way in China where GSK has the marketing rights to Viread and when it receives manufacturing and marketing approval from China's State Food and Drug Administration (SFDA) sometime likely to be in 2014.

Patients develop resistance to the major existing HBV medications over time and chronic HBV patients then need to change to a next generation therapy. In the case of lamivudine, around 80% of patients develop resistance after 5 years. In the case of adefovir, almost 30% of patients develop resistance after 5 years.

Agenix is positioned to offer very strong competition in this large medical market with our lead product candidate, AGX-1009, which belongs to the same class of drugs as Viread known as nucleotide analogue reverse transcriptase inhibitors. They work by blocking an enzyme the virus requires to replicate. AGX-1009 will be a once-a-day therapy for this market.

In October, Agenix entered into two important agreements with our strategic partners in China:

The first was with China's Institute of Pharmacology and Toxicology of the Academy of Military Medical Sciences and covers the work to complete important pre-clinical toxicology tests for our hepatitis B drug, AGX-1009, ahead of our application in mid 2012 to start human clinical trials.

The second was a cooperation agreement with the Institute of Medicinal Biotechnology (IMB) of the Chinese Academy of Medical Sciences in Beijing. This MoU may well lead to future pipeline products for Agenix as it formally documents how we can explore areas of mutual interest and cooperation in the development and commercialisation of potential new drug candidates under development by our strategic partner IMB. We are in the rare company of the Bill and Melinda Gates Foundation and only a couple of other organisations to have such an agreement with IMB.

Both agreements reinforce our commercial position in China and provide the solid foundations of long-term growth for our business in one of the world's largest and fastest growing healthcare markets.

The field of developing effective new drugs for the unmet medical needs of millions of people in the developing world is very cool, in a modern sense, and potentially very lucrative.



Also in September, our strategy to prove and commercialise an affordable once-a-day drug treatment for the symptoms of hepatitis B in China with IMB was highlighted at the annual Bio Korea conference, one of the largest international biotechnology business events in Asia.

### **ThromboView provides a better way to detect blood clots**

The independent clinical evidence to show that our lead diagnostic ThromboView is safe and effective continues to grow. During the quarter, a detailed report in the *American Journal of Respiratory and Critical Care Medicine* described ThromboView as 'not just a new diagnostic method; it is a new imaging concept.'

The report was based on the results of a 52 patient multi-centre Phase II study in the US and Canada, conducted by the University of California San Diego Medical Centre, found ThromboView was well tolerated by a range of patients and was able to accurately diagnose acute pulmonary embolism.

ThromboView was created to provide medical professionals with a better way to accurately detect deadly live blood clots and pulmonary embolisms in the human body without the exposure to high chest radiation and nephrotoxic contrast agents used by current methods.

This promising technology was also a highlight at the Fourth Annual Congress of Molecular Diagnostics in Beijing in September where there was strong interest in the data from ThromboView's two successful US Food & Drug Administration (FDA) Phase II human clinical trials.

Our discussions with groups that have expressed interest in either buying or licensing this promising asset are making good progress.

We expect these to continue into 2012. I take this opportunity to thank Professor Tim Morris from the University of California San Diego Medical Center, Dr. Mike Gerometta who has been with the project for several years and other key ThromboView® project team members as our partnering program progresses. The take-away here is that the Company believes there are no technology issues and that a successful partnering program will come down to an assessment of market size and financial capacity.

Two independent estimates of the market size for PE in the USA alone, each supported by peer reviewed literature, put PE market size at around 1.8 million tests conducted annually. The other estimate is around 2.2 million PE tests annually with an expected annual growth



rate of 3%, based on population growth, rapid growth of geriatric population and higher incidence of blood clotting with age.

Over the past year we have done an enormous amount of work articulating market positioning of ThromboView® and here's what we have figured out:

ThromboView provides accurate, functional imaging. It can be used as a replacement diagnostic test for patients with suspected PE where V/Q scans are a first-line choice and are unlikely to deliver a diagnostic result. It can be used as a confirmatory diagnostic where CT is used as a first-line diagnostic test, the scan result is negative and the clinical probability of disease is high or moderate. It can be used as a replacement diagnostic where CTPA is an inappropriate choice based on radiation exposure, renal impairment or contrast allergy. Also there is a movement to lower radiation diagnostics formalised by a recent US Joint Commission Report.

We have identified a lot of support for market penetration. There are increasing cancer rates, surgeries, and other clot related indications. ThromboView® can differentiate live versus old clots.

There is a retesting requirement when CT results are inconsistent with the recognised truth standard. In multi-slice spiral CTPA where the results are known to be suspect, 23% of patients are likely to be false positives. We think ThromboView® could take 25% of that market at peak.

Where the CT scan is positive, but there is a low pre-test probability, 3% of patients are likely to be false negatives. We think ThromboView® could take 25% of that market at peak.

Where CT is negative, but there is a high pre-test probability of a clot, 7% of CT exams are uninterpretable. We think ThromboView® could take 25% of that market at peak.

At world leading centres, 15% of CT exams are in recurrent patients. We think ThromboView® could take 15% of that market at peak.

Where multi-slice spiral CTPA may not be best choice, such as in young women. 25% of CT exams are in young women. The dose to the radiation sensitive pre-menopausal breasts is potentially dangerous.

ThromboView® has a number of advantages over V/Q including the ability to discern PE in patients with concomitant lung disorders. Also, V/Q requires precise timing between the bolus



and an immediately subsequent scan. ThromboView® does not and so avoids the dyssynchrony which results in a high proportion of non-diagnostic V/Q tests.

The *American Journal of Respiratory and Critical Care Medicine* was accompanied by an editorial that recognised this and went on to say that ThromboView®:

*“...might win the battle against V/Q lung scan in the future, and it might find a respectable, well-defined place as an alternative to CTPA in small or large groups of patients with suspected PE. As technology continues to evolve, it may become possible to use thrombus (fibrin) detection by SPECT in conjunction with low-dose thoracic computed tomography, with the potential to combine the advantages of both modalities.”...*

In the USA alone, the estimated market size for upper extremity VTE and PE alone could result in 550,000 patients annually and \$440 million in revenue.

I hope this gives you some insight into the work we have been doing and why much of it does not lend itself to public announcements.

### **Agenix is actively managing and reducing its risks**

AGX-1009 is based on an established and proven existing compound and so carries a significantly lower risk profile to a completely untested new drug compound.

ThromboView® has successfully completed five clinical trials and if we can find a partner we will partner it.

In China, we are working with strategic partners who are SFDA experts so we expect minimum errors in data and in the regulatory submissions. Also in China, we believe it is a Government priority to support new drugs like AGX-1009.

AGX-1009 has a compound patent in China to 2026. We have also filed a number of new international patent applications to protect AGX-1009 worldwide. In September we filed an application under the international Patent Cooperation Treaty (PCT) and also in some selected non-PCT countries aiming to reinforce the already long-term protection we have in China.

ThromboView is protected by broad patents in USA, EU, Singapore, Australia, and New Zealand to 2022 and patent applications are under examination in China, Canada and Japan.





These patents cover other tags, including PET. There is data exclusivity protection as a biologic for 10 years in Europe and Japan, 12 years USA, and 6 years in China from the date of regulatory approval.

The ThromboView® trade mark is registered in numerous geographies. We will continue to build and will aggressively defend these rights.

Then there is a focus on the C's, Communication with stakeholders, Costs Control, Commercialising our late stage Candidate, our active Compound for hepatitis B is known, China where we have good partners and are positioned to benefit from significant unmet medical needs.

### **The outlook for our business in 2012 is positive**

In the near term there should be two genuine value inflection points for investors: the first is a partnering or sale event for ThromboView®.

Potential partners currently conducting due diligence may conclude a deal in 2011/2012 including access to technology fees, milestone payments, royalties. That's what we are working to achieve.

The second is the formal Clinical Trial Application (CTA) filing for AGX-1009 with China's State Food & Drug Administration in 2012.

There may be also be a potential Phase I start in that program depending on how long the SFDA takes to grant approval and a possible Phase III start for ThromboView® if it is partnered. Other milestones in 2012 will include the progress of key patent applications, additional peer publications to support ThromboView and data from the pre-clinical studies of AGX-1009. We also hope to announce a number of technical, clinical and commercial opportunities to build a late stage pipeline of assets that are accretive in the near term.



## **Focus on corporate governance**

Before we move to procedural matters and the election of directors I would like to speak briefly and in general terms about our board and governance arrangements.

The Agenix board has a strong and shared commitment to achieving and demonstrating the highest standards of Corporate Governance and promoting this rigorously throughout the Group. As a board, we aim for frankness, transparency and propriety in all stakeholder and external relationships.

The company endeavours that its practices are consistent with the latest ASX Corporate Governance Council's Principals and Recommendations wherever possible. This is not always possible because, to maintain a lean and effective structure, the board is small and takes an active role in the company's affairs.

Nevertheless, risk management, governance procedures and the interests of shareholders always take precedence over collegiality. The board continues to refine and improve the governance framework and practices in place to ensure they meet the interests of all stakeholders. Details of these policies, together with Agenix's other key corporate governance policies are published on the Agenix website.

Our people in Australia, the USA and China continue to make solid progress on multiple fronts. Agenix is on the path of achieving a number of meaningful milestones for our two lead products in 2012.

I believe the continued good results we achieve together will underpin the creation of significant long term value for shareholders. Looking forward, our aim is to build on our success and to take advantage of the significant opportunities that exist for the Company.

While there are certain to be challenges within the broader market, we aim to keep our business foundations strong as we enter the next growth phase of our business and work to create long term value for shareholders. Thank you for your ongoing support of our company.

Nicholas Weston  
Chairman and CEO  
31 October 2011