### **AGENIX LIMITED**







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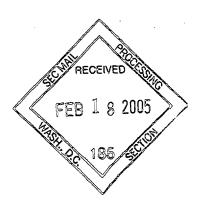
82-34639

SEC#82-5258

1 February 2005

US Securities and Exchange Commission Attention: Filing Desk 450 Fifth Street NW WASHINGTON DC 20549 USA

Dear Sir





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# Re: Submission Under Rule 12g3-2(b) - Agenix Limited

We refer to the attached announcement that was made to the Australian Stock Exchange on 1 February 2005.

We are providing a copy of this announcement by virtue of our requirements under Rule 12g3-2(b).

Yours sincerely

Neil Leggett

Company Secretary



# ThromboView® Investor Update

1 February 2005

The ThromboView® project continues to meet our expectation that we will deliver a product that will fill an unmet medical need in the detection of Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE), and produce global sales annually of A\$570 million plus and profit after tax of A\$200 million plus.

The following update on the status of the ThromboView<sup>®</sup> program as at the end of January 2005 is intended to provide guidance to investors on key activities and programs currently underway. As always, key events of a material nature will continue to be communicated as they occur.

For ease of reference, a glossary is included at the end of this update.

#### Highlights:

- · Completion of live phase of DVT safety studies
- Upgrade of Brisbane laboratories to a world class biological manufacturing facility licensed to
  manufacture clinical trial material for ThromboView® and future projects, thereby reducing costs,
  minimising time delays and optimising existing capital assets
- Successful regulatory submissions to US Food and Drug Administration (FDA) and Health Canada, validating our clinical protocols and manufacturing standards
- Successful manufacture of ThromboView<sup>®</sup> to US FDA standards for Phase II trials by Baxter Pharmaceutical Solutions (Indiana, USA)
- Commencement of Phase II DVT clinical trial at sites in US and Canada

### Expected Developments in the next 12 Months

- Injection of first patient in Phase II DVT study in February 2005.
- Release of final report on Phase Ib DVT safety study by March 2005
- Commencement of Phase Ib PE study by May 2005.
- Commencement of Phase II PE study by September 2005
- Negotiation of ThromboView<sup>®</sup> licensing deal with global diagnostic imaging companies.
- Leveraging our clinical and manufacturing capabilities to expand our cardiovascular product pipeline to other cardiovascular conditions (eg stroke) and to other imaging modalities (eg MRI)
- Leveraging our clinical and manufacturing capabilities to expand our product pipeline in other medical areas (eg oncology)

## Overview

Significant value-adding activities have been undertaken in the 2004 calendar year and our investment in the development process continues to be guided by rigorous assessment of product performance against pre-determined critical milestones.

Successful regulatory submissions to the United States Food and Drug Administration and Health Canada, which demonstrate the acceptability of our clinical protocols and manufacturing standards, were a highlight of the 2004 year.

We completed the live phase of our Phase Ia and Ib DVT safety studies and are now commencing Phase II DVT clinical trials which will guide assessment of ThromboView<sup>®</sup>'s ability to deliver on the promise of functional clot imaging in both DVT and PE.

We remain confident and excited that the active ingredient of ThromboView<sup>®</sup>, the humanized 3B6 D-dimer antibody, which has demonstrated very high sensitivity and specificity for clot-resident D-dimer domains, will enable doctors to more accurately determine the presence of clot compared to current anatomical imaging methods. This, in turn, will guide more accurate therapeutic decision-making and limit the sometimes devastating consequences of mis-diagnoses.

# ThromboView® Clinical Program - Phase I Trials

Two Phase I trials determining the safety profile of ThromboView® in healthy volunteers and DVT patients have been undertaken and provide the confidence and rationale for moving forward with further clinical development in Phase II trials. Data analysis for the Phase Ib DVT study is now substantially complete with the final clinical study report in preparation. Importantly, the Phase Ib DVT study showed that ThromboView® images clot in clinical sites of interest and is not associated with toxicity which allowed us to progress to Phase II trials without waiting for the complete report to be available. The preparation and management of the Phase II clinical trials has had to take priority over this report.

An additional Phase Ib PE study will be undertaken in Australia to gather baseline safety data in patients with embolised clot. This study will draw on the expertise and skills of investigators already familiar with ThromboView®, as well as including additional trial sites to boost recruitment rates, and allow an assessment of the success of product optimization programs to accurately locate and identify clot in the chest. This study will run concurrently to initiation of the Phase II DVT program and reinforces our intent to differentiate ThromboView® as an agent well capable of detecting venous thromboembolism in both lungs and legs.

To support the expansion of the ThromboView<sup>®</sup> clinical development program we have boosted resources in our clinical research group. Two experienced clinical research managers now have responsibility for managing the DVT and PE clinical trials. We believe that the addition of staff to the clinical program delivers a structure which provides greater focus and capacity to managing the many tasks involved in initiating and executing a trial program. The completion of these trials within our current timeline is a priority for the entire team.

# ThromboView® Phase II Manufacture

An upgrade of manufacturing facilities at our Brisbane, Australia laboratories was critical to the successful manufacture of the active ingredient for Phase II trials, and has provided the company with a substantial resource applicable to future projects. Documentation detailing manufacturing and testing methods was submitted and accepted by the US FDA and Health Canada, indicating our adherence to stringent regulatory standards governing biological manufacturing processes. We believe our in–house expertise in regulatory and technical skill sets is second to none and rewards the investment in personnel which support both the ThromboView® project and pipeline projects under review. Technology associated with the lyophilisation and fill/finish of active ingredient was successfully transferred to Baxter Pharmaceutical Solutions (Indiana, US), who have completed the manufacture of ThromboView® for Phase II trials to US FDA standards.

The ability to manufacture active ingredient for the current clinical trials delivered significant value to the company and provided an opportunity to optimize use of capital resources. Further, an additional timeline and cost benefit has been derived by avoiding excessive delays associated with commercial manufacturing lead times and costs at this early stage of product assessment and review. As we anticipate successful achievement of product performance milestones, preferred contract manufacturing organizations have already been identified and selected. We will contract with these organizations and begin the transfer of manufacturing processes to them at the correct time to enable delivery of the Phase III material on a "just in time" basis.

The development team is continually driving product improvement and optimization programs to meet the needs of a large and rapidly growing market. We anticipate these programs will deliver improved manufacturing yields and improved product performance allowing reductions in manufacturing cost and providing greater scope for market adoption.

## ThromboView® Clinical Program - Phase II Trials

We eagerly await 'first patient in' to the Phase II DVT program. Administrative activities with trial sites (necessary prior to activation of live phase) are substantially underway with many sites now close to completion. The timing of these activities over the Christmas and New Year period has increased the duration of this phase. These activities include submission and approval of institutional review board applications at the 12 sites participating in this study. Our group of investigators remain enthusiastic and keen to commence patient recruitment and study start-up is expected within the month of February. This study will assess the diagnostic accuracy of ThromboView® in the detection of initial and recurrent DVT with the 'gold standard' diagnostic modality, contrast venography. 150 patients will be evaluated in this study.

Substantial work has been completed in the lead-up to commencement of Phase II trials in the diagnosis of PE. A commercial clinical research organization has been appointed to fully manage this study and we are confident that the employment of such a group will deliver the trial results in a timely and efficient fashion. We continue to work with relevant regulatory agencies to ensure the trial protocol meets the requirements to support a label claim for ThromboView® in the diagnosis of pulmonary embolism. No other diagnostic imaging agent is approved for this indication and we intend to exploit the unique benefits of ThromboView® to capture significant competitive advantage.

These studies are all to be completed under the open US FDA Investigational New Drug filing currently in place.

### Commercial Potential

The incidence of venous thromboembolism escalates significantly with advancing age. As a general rule of thumb, clinically recognised DVT and/or PE occurs in about 1.5 in 1000 persons each year but rises to 1 per 100 in the elderly. Thus, an aging population, well-provided for by modern healthcare services, is the dominant factor underpinning growth forecasts of diagnoses associated with venous thromboembolism. We expect diagnoses of thromboembolism to grow at least 5% per year over the next 10 years in western populations.

Diagnostic challenges remain in the detection of venous thromboembolism. There is scope for an agent with the expected characteristics of ThromboView® to provide an accurate diagnosis in a wide range of patients where current technologies are inadequate or unsuitable. ThromboView® is the only technology under development that may accurately identify clot in both DVT and PE. Whilst other imaging modalities such as Doppler ultrasound and Computerised Tomography (CT) are expected to dominate in detection of DVT and PE respectively, market penetration models show that even with modest peak projections 7 years post-launch, expected global sales of ThromboView® are upwards of A\$570 million. We will continue to refine market models and forecasts as clinical data become available and as our competitive position becomes clear. However, we remain confident that ThromboView® will meet important unmet medical needs in the diagnostic management of patients with venous thrombosis, and provide doctors with critical information to better guide treatment decisions and positively impact the care of patients with this disease.

ThromboView® continues to meet our expectations and deliver the performance that we believe will ensure it's success. Agenix is committed to delivering a product to the medical community that has the ability to accurately identify both DVT and PE in those patients where the current testing modalities fail to do so thus significantly improving the management of this disease.

Glossary

DVT Deep vein thrombosis. The formation of blood clots within large veins

(normally in the legs) leading to obstruction of blood flow. DVT can be painful

but not fatal.

**FDA** Food and Drug Administration. The US government agency responsible for

regulating the food and drug industry. The Australian equivalent is the

Therapeutic Goods Administration (TGA).

Humanised 3B6 D-dimer The original 3B6 D-dimer antibody (mouse) was patented by Agenix in 1984

> to detect a specific protein that only occurs in clotting blood. It is used in all the thrombosis diagnostic tests sold by Agenix's Human Health business, and uses a few drops of patient's blood to test for abnormal levels of clotting. These tests are in vitro - they are conducted outside the body. Because ThromboView® is an *in vivo* test – it is injected into the patient to locate blood clots - a new version of the antibody has been created that is humanized and

is safe for human use.

IND Investigational New Drug (Application or filing). An IND is reviewed by the

FDA for the suitability and safety of the drug and trial design for human

Lyophilisation and fill/finish The final steps in the manufacturing process where the antibody is dispensed

into the final vials in a measured dose, frozen and dried under vacuum. This process enables the product to remain stable for many months or years prior

Imaging Modalities The method of imaging a disease. X-ray is a common imaging modality -

other modalities include:

A chemical is injected into the body and imaged with X-ray. The resulting Contrast venography

image can show blockages in those veins. It is a painful and operator

dependant technique.

- CT Computed Tomography. Combines numerous X-ray images into a single

image that is much more precise than conventional X-rays and provides

increased detail.

Magnetic Resonance Imaging: A large magnet and radio waves use the

electric energy in the body's cells to create an image of structural defects,

especially in soft tissues.

- Ultrasound High-frequency sound waves are bounced off soft tissues, and the echoes

are converted into a picture.

PE Pulmonary embolism. The lodgement of clots or other particles in the blood

vessels of the lungs, often as a result of a DVT clot breaking free and

travelling through the bloodstream to the lungs. PE can be fatal.

New drugs are required to successfully pass three clinical trial phases before Phase la, lb, and II

regulators will approve the drug for human use. Very broadly speaking phase I (a and b) determines if the drug is safe, Phase II tests for the appropriate dose, and Phase III provides a final check how well it performs on a larger

number of patients before the drug is commercialised.

Diagnostic tests need high sensitivity and specificity to give doctors Sensitivity and specificity

confidence in the results. Sensitivity is a measure a test's ability to correctly diagnose a patient with a certain disease and specificity is a measure of a test's ability to correctly diagnose a patient who does not have the disease.

- MRI