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**AGENIX LIMITED**  
11 Durbell Street P.O. Box 391  
Acacia Ridge QLD 4110  
Australia  
Tel : +61 (0)7 3370 6396  
Fax : +61 (0)7 3370 6370  
Website : www.agenix.net

**SEC#82-5258**



16 June 2004

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

**SUPPL**

Dear Sir

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

We refer to the attached announcements that were made to the Australian Stock Exchange on 9 June, 11 June and 16 June 2004.

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

Yours sincerely

Neil Leggett  
Company Secretary

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**PROCESSED**

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FINANCIAL



## ASX ANNOUNCEMENT AND MEDIA RELEASE

9 June 2004

### **Agenix upgrades valuation of ThromboView®**

Biotechnology company, Agenix Limited [ASX: AGX, NASDAQ OTC: AGXLY] today announced it had significantly upgraded its projected sales and valuation of its innovative, blood-clot imaging technology, ThromboView®.

The company has increased its projected peak sales of ThromboView® from approximately A\$320 million to A\$570 million within eight years of launch and the projected profits after tax attributable to ThromboView® at peak sales from A\$64 million to around A\$200 million.

Following the upgrade in projected earnings, Agenix has also increased its valuation of ThromboView® to A\$180 million.

ThromboView® uses radiolabelled antibodies to locate blood clots in the body. Its development targets the US\$3 billion global clot diagnostic imaging market.

The valuation upgrade follows the completion of an independent report into the company's commercialisation plan and financial model for ThromboView® by Dr William Ramage, a US-based specialist in the business development and marketing of diagnostic imaging technology, with more than 20 years experience in the field. This report was commissioned during the Peptech merger due diligence period. Following termination of the merger, details have been released in the interests of keeping the market up to date with the latest available information relevant to Agenix's lead candidate in servicing the acute phase thrombosis market.

Dr Ramage's report found that both Agenix's commercialisation plan and financial model for ThromboView® were reasonable and had a probability of success which is equal to or higher than other pharmaceutical products at an equivalent development stage.

Agenix Managing Director Mr Don Home said Dr Ramage's independent report gave the company great confidence in the global potential for the product.

"The independent report by Dr Ramage supports the validity, reliability and robustness of the commercialisation plan and financial model we are applying to the development of ThromboView®," Mr Home said.

"ThromboView® is a key part of our strategy going forward to service the global acute phase thrombosis market.

"We have absolute confidence in the strength of our highly experienced management team, our quality products and internationally recognised manufacturing infrastructure."

Mr Home said the company will continue to refine assumptions and projections for ThromboView® as more information is gathered throughout the clinical trials process and look at what additional market segments ThromboView® can serve.

"After just three years of development, we have progressed a high-technology product from an idea to something which has the opportunity to address a global demand," he said.

"This is a great outcome for Agenix shareholders."

A key potential competitive advantage of ThromboView® over other imaging technologies is its potential ability to image both Deep Vein Thrombosis (DVT)(blood clots in the legs) and pulmonary emboli (PE)(blood clots in the lungs) using a single test. PE is the third largest cause of cardiovascular death after heart attacks and stroke and kills an estimated 60,000 each year in the US alone.

ThromboView® is currently being evaluated in an ongoing Phase Ib trial to examine its safety and dosimetry in patients with proven DVT.

Encouraging preclinical data and the interim results from its Phase Ib trial indicate that ThromboView® may also be able to image pulmonary emboli (PE).

Agenix Scientific Advisory Board Chairman Professor Paul Eisenberg said that as a result of the findings during the Phase Ib study, the team was eager to move rapidly into Phase II trials to test the ability of ThromboView® in the diagnosis of both DVT and PE.

Agenix has earlier announced its decision to proceed with the Phase II trial of ThromboView® in DVT in North America.

"We continue to believe that ThromboView® has the potential to address important unmet medical needs in the diagnosis of patients with both DVT and PE using a single test," Professor Eisenberg said.

Mr Home said the company sought the opinion of Dr Ramage on ThromboView® based on his more than 20 years experience in the imaging market, including executive roles with DuPont Merck and Molecular Biosystems Inc, and his recent five years experience as a consultant conducting due diligence on global imaging programs.

The key findings of the report are:

- Given the projected high diagnostic accuracy of ThromboView®, when marketed appropriately as suggested in the Agenix plan, it should be able to capture 5 to 10 percent of the market for venous thromboembolic testing over a 5-6 year period post launch and command a modest premium compared to other similar nuclear medicine products.
- Agenix has a sophisticated understanding of; the market for venous thromboembolic diagnostic imaging, the number of procedures done in major countries, the advantages and disadvantages of these existing tests and the significant unmet medical needs.
- Agenix should be able to optimise the clinical trials not only to produce information necessary for regulatory approval, but also to support cost effective marketing.
- Revenue from potential marketing partnership opportunities for marketing and distribution rights in Europe and Japan is potentially much higher than previously projected.
- Agenix has developed a rigorous set of preclinical and clinical data which adequately supports moving the product into additional human clinical trials.
- The review of the program confirmed the overall high quality of the preclinical and clinical procedures that have been used by Agenix in this program

The Phase II clinical trials for ThromboView® will be performed under an Investigational New Drug application to be filed with the US Food & Drug Administration (FDA) in the second half of 2004 and Clinical Trial Application (CTA) in Canada.

It is likely the first patients will participate in the Phase II trials later this year.

- ENDS -

**For further information, please contact:**

Donald Home  
Managing Director  
Agenix Limited  
Ph: 0438 500 255

**Agenix Limited [ASX:AGX, NASDAQ OTC: AGXLY]** is a listed company based in Brisbane, Australia. It manufactures, distributes and markets human and veterinary diagnostic test kits, over-the-counter pharmaceuticals and infant-care products via its wholly-owned subsidiaries AGEN Biomedical and Milton Pharmaceuticals. Agenix focuses on developing a horizontally integrated product portfolio to service the needs of the acute phase thrombosis market. Agenix's lead candidate is its high-technology ThromboView® blood clot-imaging project, which is currently undergoing human trials. ThromboView® uses radiolabelled antibodies to locate blood clots in the body. It could revolutionise the US\$3 billion global clot diagnostic imaging market. ThromboView® is being developed with the assistance of the Federal Government through its START scheme. Agenix employs 200 staff and sells its products to more than 50 countries. ThromboView® is a registered trademark of AGEN Biomedical.

[www.agenix.com](http://www.agenix.com)

**Background: Dr William Ramage**

Dr Ramage was awarded a Doctor of Philosophy by the University of Oxford, England and holds a Bachelor of Science from the University of Glasgow, Scotland.

He joined Dupont Merck Pharmaceutical Company (now known as Bristol Myers Squibb) in 1979 and after success in marketing products including Cardiolite and I.V. Persantine and establishing a strategic alliance with Syncor, rose to the position of Vice President, Business Development and Customer Services.

In 1996, he joined Molecular Biosystems Inc as Vice President of Marketing and Business Development responsible for the launch of Optison, a successful diagnostic imaging product.

Since 1999, Dr Ramage has consulted to companies in the biotechnology, diagnostic imaging and drug delivery fields providing strategic advice on sales, marketing, business and corporate development, distribution, strategic alliances and raising funding.

**Report by Dr William Ramage: Overview of methodology and assumptions**

Dr Ramage reviewed a financial model produced by Agenix's management team which depicted a likely cash flow scenario based on potential market size and share and their assessment of realistic expenses. A discounted cash flow analysis of the company's financial model was then used to arrive at a net present valuation of the projected cash flows, using a discount rate which reflected the overall risk of the ThromboView® program.

The projected revenue from ThromboView® contained in the commercialisation plan and financial model was derived principally from data supplied by Arlington Medical Resources' six month audit of all imaging procedures done in the US and in certain parts of Europe. In addition, the following revenue assumptions were made:

- The target market for ThromboView® varies both geographically and depending on whether it is attempting to diagnose DVT or PE but overall represents approximately 10% of the total imaging market
- ThromboView® will have a global market principally, the US, France, Germany, Italy and Japan. These geographical markets were determined after considering the number of procedures carried out in the USA, Europe, Japan and the rest of the world for each of DVT and PE
- Peak market penetration of ThromboView® is achieved in 2016/2017 being approximately 7% of the total market
- ThromboView® will be priced at a modest premium compared to other similar nuclear medicine products
- The number of procedures done per year grows at 5% per year
- Revenue will be sourced from sales to end users as well from payments from sales and marketing partners
- ThromboView® will compete on both the DVT and PE diagnostic testing markets
- There are no new significant entrants or new competing technologies adopted by the market in the projection period.

The following key cost assumptions were made or taken into account:

- Clinical trial costs were based on reliable estimates provided by contract research organisations to Agenix
- Product for Phase II and III studies and subsequent commercial production will be undertaken in the US in a FDA licensed facilities, but with the company being responsible for final quality assurance
- The marketing and distribution costs in the US were comparable with similar products
- Licence fees and royalties will be payable for technology used in or incorporated into ThromboView®.

Other key inputs and assumptions were:

- Cash flow projections were determined from 1 July 2003 and the valuation period is 14 years. A residual value was determined by applying the discount rate to the net cash inflow for the 2016/17 year.
- The discount rate was 25%
- The AUD:USD exchange rate was 74 cents
- US FDA approval for DVT and PE and product launch in March 2008
- Revenue within 1 year of launch
- Marketing in the rest of the world commences in 2010
- Company tax at the rate of 30%.



**AGENIX**

## Company Announcement

### **AGEN Biomedical secures worldwide distribution partnership with Inverness Medical Innovations**

11 June 2004

Brisbane-based biotechnology company Agenix Limited [ASX: AGX, NASDAQ OTC: AGXLY] today announced that its wholly owned subsidiary AGEN Biomedical Limited had signed an exclusive worldwide distribution agreement with US based Inverness Medical Innovations Inc (Amex: IMA) for its *Simplify*<sup>™</sup> D-dimer test.

Under the partnership, Inverness Medical — one of the world's largest and leading manufacturers and marketers of rapid diagnostic products — will have worldwide exclusive rights to distribute the test kit through its two wholly owned subsidiaries, Wampole Laboratories and Unipath.

Agenix Limited Managing Director Mr Don Home said the distribution agreement was a major breakthrough for AGEN in serving the acute phase thrombosis market globally.

"This collaboration is a significant commercial coup for AGEN. Importantly, it provides the best partner to take *Simplify*<sup>™</sup> to the growing market," Mr Home said.

"Through Inverness, we can get *Simplify*<sup>™</sup> directly into the hands of the hospitals, hospital buyer groups and doctors who are demanding this type of diagnostic test.

"The Wampole and Unipath networks give us access to up to 1,000 representatives to market our product."

AGEN has been executing its strategic plan for D-dimer globally over the past several years by positioning itself as the gold standard for D-dimer testing based around the 3B6 antibody. It has now secured global alliances with some of the largest and best multinational diagnostic companies representing all the key diagnostic disciplines:

1. Immunodiagnostics based – Dade Behring, Diagnostic Products Corporation
2. Coagulation market – Diagnostica Stago, Instrument Laboratories, bioMerieux
3. Point of care instrument based with Biosite
4. Point of care – rapid assays with Inverness.

"With the addition of Inverness, we've got all the key market sectors covered," Mr Home said.

"Inverness is in an extremely powerful position in the marketplace –it dominates the international rapid point of care testing market, and has outstanding sales and marketing capability around the world."

Agenix is forecasting growth in sales volume of the *Simplify*<sup>™</sup> D-dimer test by up to four times in the first 12 months to \$2.5 million. Sales projections for the following two years also anticipate increases by a minimum of 100 percent per annum.

"These are conservative forecasts and in the next few months we expect these will be upgraded once further training is conducted with the Inverness team," Mr Home said.

The *Simplify*<sup>™</sup> D-dimer test, based on AGEN's patented specific monoclonal antibody for D-dimer, DD3B6/22, delivers a rapid D-dimer measurement for a whole blood or plasma sample using a simple lateral flow self performing assay format. This format is ideally suited for near patient testing allowing a positive result to be available in one to two minutes particularly in critical care settings such as Emergency Departments and doctors offices where the speed of information can significantly improve patient outcome.

D-dimer is one of the smallest proteins arising directly from the body's natural mechanism to break down blood clots. Elevated levels of D-dimer in a patient's blood are indicative of abnormal rates of clotting. AGEN Biomedical's *Simplify*<sup>™</sup> tests for D-dimer aid practitioners in diagnosing blood clot conditions.

AGEN Biomedical Vice President Human Health Gregg Mastroianni said the signing of the five year distribution agreement (with automatic annual renewals) was one of the most important milestones in the history of AGEN's unique D-dimer tests since the 3B6 antibody was patented in 1982.

"This arrangement provides us with an excellent partner to maximise the penetration of *Simplify*<sup>™</sup> into these markets," he said.

"D-dimer demand continues to grow throughout the world as a result of increased public and medical community awareness. Through this global distribution agreement, we can leverage our portfolio of D-dimer intellectual property to capitalise on this anticipated increased demand."

Distribution of the *Simplify*<sup>™</sup> D-dimer test by Inverness Medical will commence next month, when the product will also be showcased to the international medical community at the American Association of Clinical Chemists meeting in Los Angeles (July 26). This meeting is the largest annual gathering of pathologists and medical scientists in the world.

## **ENDS**

### **For more information contact:**

Mr Donald Home  
Managing Director  
Agenix Limited  
Ph: 61 7 3370 6300

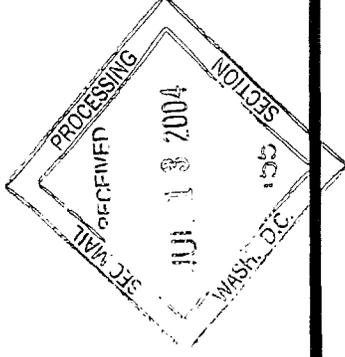
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**Inverness Medical Innovations (AMEX:IMA)** is a leading global developer of advanced diagnostic devices and is presently exploring new opportunities for its proprietary electrochemical and other technologies in a variety of professional diagnostic and consumer-oriented applications including immuno-diagnostics with a focus on women's health, cardiology and infectious disease. The Company's new product development efforts, as well as its position as a leading supplier of consumer pregnancy and fertility/ovulation tests and rapid point-of-care diagnostics, are supported by the strength of its intellectual property portfolio. The Company is headquartered in Waltham, Massachusetts.

[www.invernessmedical.com](http://www.invernessmedical.com)

**Deep Vein Thrombosis** is a common condition that can be extremely painful and life threatening and if left undiagnosed can result in pulmonary embolism. Accurate and early diagnosis of blood clots is important, because it minimises the risk of complications and averts the exposure of patients without thrombosis to the dangers of anticoagulant therapy.

However, accurate detection of blood clots is a major problem for the medical community. Blood clot symptoms can be very vague and only around one-quarter of all patients presenting with symptoms have the disease confirmed. Diagnosis of clots is predominantly undertaken by radiologists who use imaging tests to confirm or rule-out disease. Current imaging tests are expensive and time-consuming and may not deliver an accurate result in certain types of patients. Therefore, a rapid, inexpensive, non-invasive and sensitive blood test, such as AGEN Biomedical's *Simplify*<sup>™</sup> D-dimer test, is of great interest to the medical community to reduce the burden on radiology resources, improve quality of patient care and improve diagnostic accuracy.



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# Agenix Limited

Donald Home  
Managing Director

Presented: 16 June 2004

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# Strategic blend

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- Commercial foundation
  - Manufacturer and seller of Animal and Human Health diagnostic products that are leaders in their niche markets
- Biotechnology investment
  - Research and development of ThromboView<sup>®</sup>, innovative blood-clot imaging technology targeting a global US\$3 billion market



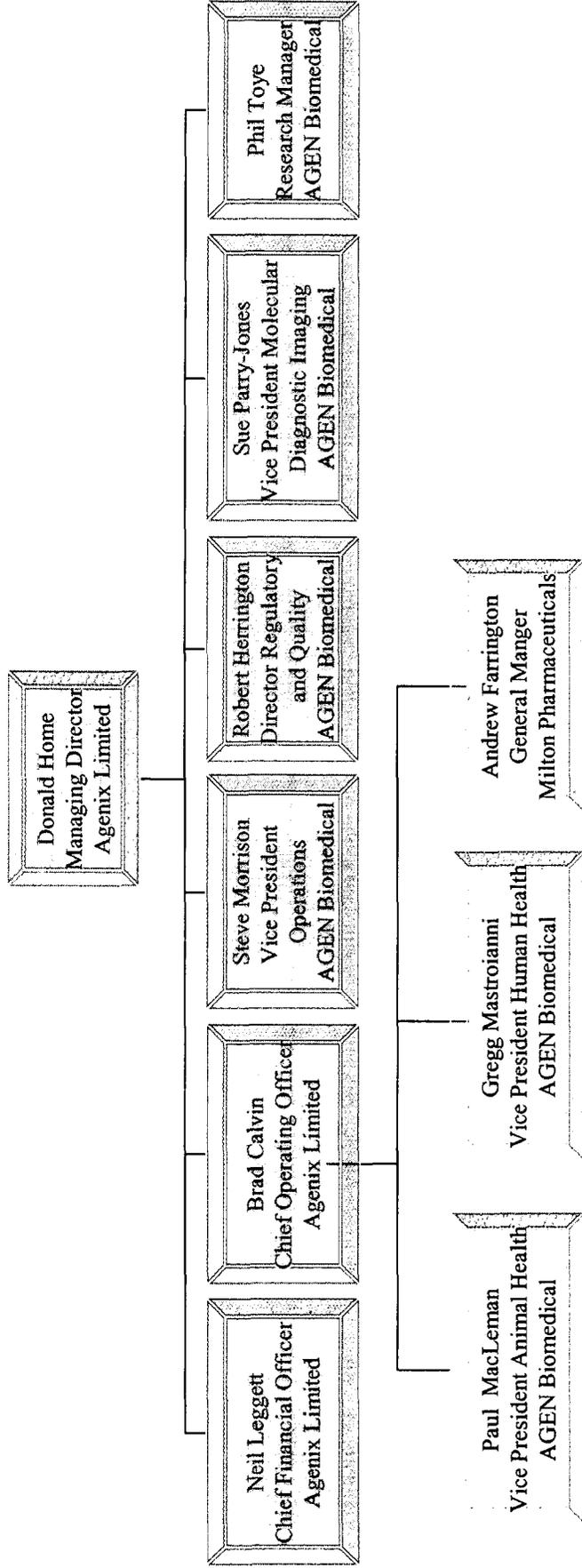
# Overview of Agenix

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- Incorporated January 1987
- Listed on ASX October 1987
- Established Level 1 ADR facility June 2002
- Joined S&P/ASX 300 index June 2003
- Over 200 staff
- Products distributed to more than 50 countries
- Infrastructure and manufacturing facilities in Brisbane approved under FDA, USDA and TGA
- Completed 2 year rationalisation and consolidation process in FY2004



# Agenix Management





# Management Biographies

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**Don Home** – 15 years with Abbott Laboratories, including 5 in Chicago, USA, 3 years as CEO of Agenix.

**Brad Calvin** – 14 years with Abbott Laboratories in commercial roles in US, Europe and Middle East

**Neil Leggett** – 16 years Chartered accountancy experience and 13 years senior commercial positions including CFO and Company Secretary roles.

**Andrew Farrington** – 14 years senior management experience with Woolworths and Unilever and 2 years as General Manager of Colourcorp

**Gregg Mastroianni** – 32 years experience with J&J in the US, Japan and Europe in national and international Sales and Marketing roles

**Paul Macleman** - A veterinarian with international clinical experience with several years as General manager of Nature Vet and Investment Banking

**Sue Parry-Jones** – 20 years experience in the biotechnology/pharmaceutical industry with Bristol-Myers Squibb, Amgen and Schering-Plough

**Steve Morrison** – 17 years experience with Fauldings/Mayne Pharma in Australia and Puerto Rico in Manufacturing and Quality management

**Robert Herrington** – 30 years experience in the pharmaceutical industry, mostly with CSL in senior international regulatory roles

**Phil Toye** – 20 years in various research and development positions in the areas of parasitic vaccines and diagnostics at Harvard Medical School and ILRAD



# Corporate developments

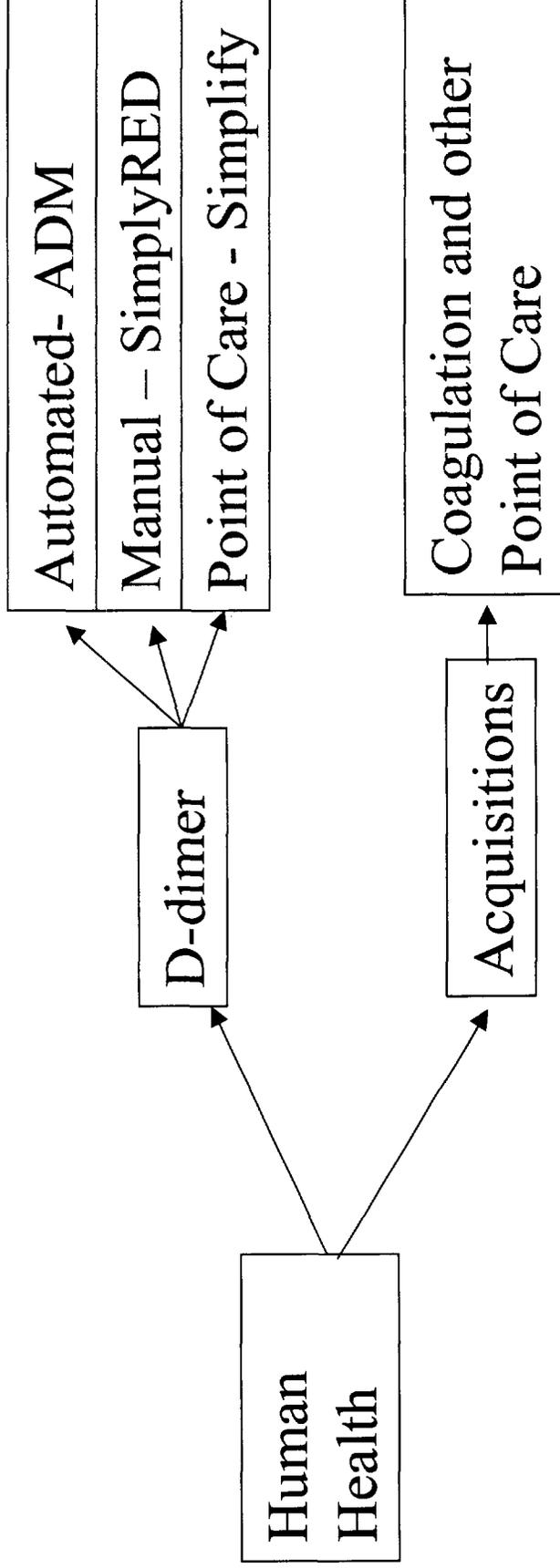
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- **Proposed merger with Peptech Limited not proceeding**
  - Issues surrounding Peptech valuation of Centocor
  - Better options for growing Agenix
  - Investigating new acquisition and partnering opportunities
  - Confidence in corporate strategy and Thrombo View<sup>®</sup> to proceed independently



# Key Market Areas - Human

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# Human Health - Recent developments

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## Inverness Distribution Agreement

- Exclusive worldwide distribution agreement with US based Inverness Medical Innovations Inc for Simplify D-dimer test
- D-dimer market at US\$75MM and growing by 10-15%pa
- Agenix is a world leader in D-dimer clot diagnostics
- Inverness leader in the international rapid point of care testing market
- Adds to other global alliances with some of the largest and best multinational diagnostic companies to now cover all key market sectors



## Animal Health - Recent developments

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- Expect resolution of patent-related legal action against Synbiotics within the next month
- Sales to US based animal health distributor Vedco (appointed September 2003) running according to forecast
- Will appoint additional new distributors in US



# Lead candidate - ThromboView®

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- Unique direct binding of radioactive labelled antibody to blood clots
- Competitive advantage in its potential ability to image both Deep Vein Thrombosis (DVT) and Pulmonary Emboli (PE) in one test
- Target market
  - Worldwide annual US\$3 billion clot imaging market
  - DVT – 2 million cases per year in the USA (if untreated 30% probability of progressing to Pulmonary Embolism )
  - PE – 600,000 cases per year in the USA (90% caused by DVT)
- Addresses a significant unmet market need to rapidly and accurately identify PE



## Lead candidate - ThromboView®

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- Low technical risk: antibody is humanised and labelling is completed
  - High probability for approval: commonly used antibodies and Technetium label
  - Strong IP position – patent pending in National Phase
  - Expected launch by 2008
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## Thrombo View® - recent developments

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### Positive Independent Expert Report

- Report by Dr William Ramage supports the validity, reliability and robustness of the commercialisation plan
- Probability of success rated at equal to or higher than other pharmaceutical products at an equivalent development stage
- Potential to capture 5-10% of US\$3b market within 5-6 years of launch and command premium



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# ThromboView<sup>®</sup> - recent developments

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## Phase II clinical trials to commence later this year

- Phase Ib trial into safety and dosimetry with proven DVT patients ongoing
    - Demonstrated targeted delivery to the clot
  - Study on use in healthy patients found no adverse effects or evidence of immune activation
  - Phase II to be performed under an Investigational New Drug application to be filed with FDA in 3<sup>rd</sup> Qtr 2004 and Clinical Trial Application in Canada
  - Contracted Baxter Healthcare to manufacture final material for trials
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# Financial Plan

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- Focus on driving international sales growth for Animal Health and Human Health products
- Current and projected group financial resources to cover Thrombo View<sup>®</sup> expenses until launch
- Expenses managed to improve profile
- Reduced net profit after tax reflects increased R&D expense and infrastructure to support added complexity of business.



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## Operating Revenue - commentary

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- Reflects only 3 month contribution by Vedco (appointed September 2003)
- Impacted by delays in product shipment



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# Cash Flow from operations before R&D – Half Year

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- \$1.5m invested in additional infrastructure and a quality improvement plan to support the business
- Agen upgrades sales and production processes preparatory to imminent product revenue increases.
- Agen invests in computer applications for documentation handling to reduce future outsourcing costs.
- Agen incurs legal costs to defend US animal health market position.



# AGENIX Non-recurring items impact on current EBITDAR – Half Year

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- Agen upgrades sales and production processes and quality systems preparatory to imminent revenue increases.
- Agen incurs legal costs to defend US animal health market position.
- Agen animal health sales in US down due to legal dispute.
- Agen acquires licenses from Abbott Laboratories.



AGENIX

# Contact us

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Don Home  
Managing Director  
Agenix Limited  
11 Durbell Street  
Acacia Ridge Qld 4110  
Ph (07) 3370 6396  
Fax (07) 3370 6347  
Email: [dhome@agenix.com](mailto:dhome@agenix.com)

Website: [www.agenix.com](http://www.agenix.com)