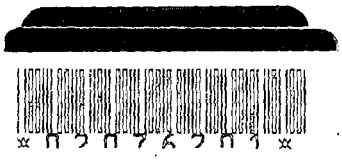


# 82- SUBMISSIONS FACING SHEET

MICROFICHE CONTROL LABEL

REGISTRANT'S NAME VRI Biomedical Limited

*CURRENT ADDRESS Level 11, BGC Centre
28 The Esplanade
Perth, WA 6000
Australia

**FORMER NAME

**NEW ADDRESS



FILE NO. 82- 34683 FISCAL YEAR 6/30/01

* Complete for initial submissions only ** Please note name and address changes

INDICATE FORM TYPE TO BE USED FOR WORKLOAD ENTRY:

| | | | |
|---|---|---|---|
| 12G3-2B (INITIAL FILING) | X | AR/S (ANNUAL REPORT) | X |
| 12G32BR (REINSTATEMENT) | | SUPPL | |
| DEF 14A (PROXY) | | | |

OICF/BY: GBS

DATE : 9/20/02

# Annual Report

2001

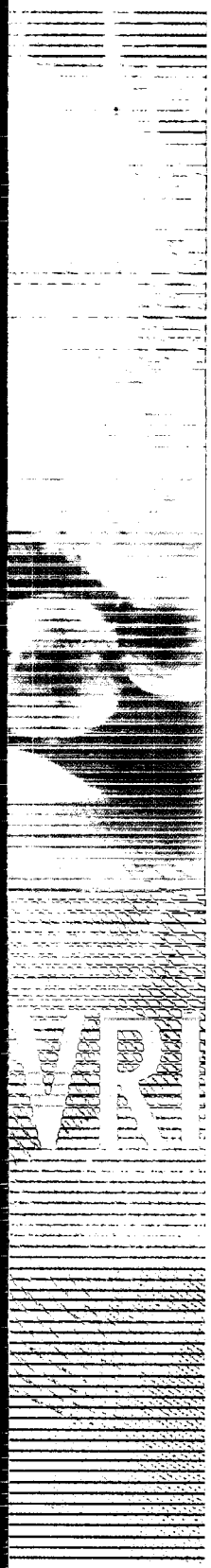
VRI
BioMedical

A.B.N. 97 084 464 193

VRI BioMedical

# VRI BioMedical Limited

## Corporate Information



**Directors**
Leon Ivory (Chairman)
Kenneth Peter Baxter
John Francis Cade
Robert Llewellyn Clancy
Kim Robert Slatyer
Glyn Michael Tonge

**Company Secretary**
John Richard Frame

**Corporate Head Office**
Level 11, BGC Centre
28 The Esplanade
PERTH WA 6000
Telephone: (08) 9321 3655
Facsimile: (08) 9321 3650

**Solicitors**
Freehills
Hunt and Hunt

**Bankers**
Bank of Western Australia Limited
Commonwealth Bank of Australia Limited
Macquarie Investment Management Limited

**Share Register**
Computershare Investor Services Pty Ltd
Level 2, Reserve Bank Building
45 St George's Terrace
PERTH WA 6000
Telephone: (08) 9323 2000
Facsimile: (08) 9323 2033

**Registered Office**
8th Floor
19 Pier Street
PERTH WA 6000
Telephone: (08) 9325 2411
Facsimile: (08) 9325-5520

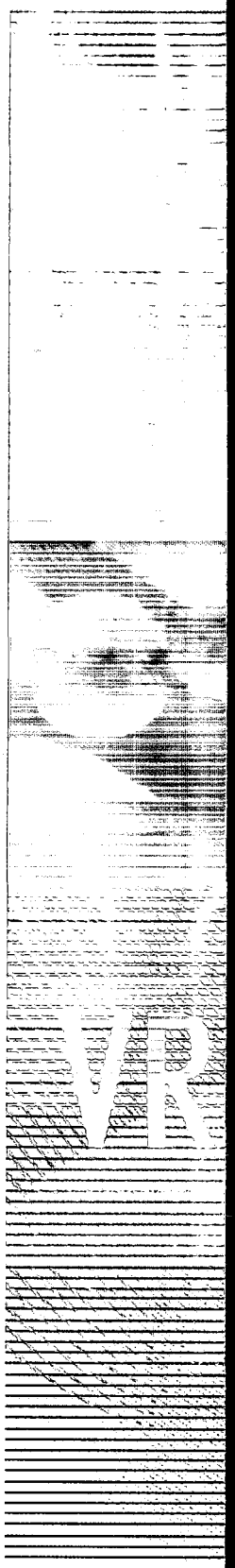
**Patent & Trade Mark Attorney**
Baldwin Shelston Waters

**Auditors**
Ernst & Young

**Internet Address**
www.vribiomedical.com

# Contents





# Dear Shareholders

It is with great pleasure that I present VRI BioMedical's 2000/2001 Annual Report to you, our first since listing on the Australian Stock Exchange (ASX) in December 2000.

VRI BioMedical has finished its first seven months as a publicly listed company having achieved excellent results and negotiated joint venture/collaboration arrangements as planned.

Following a successful Initial Public Offering where $12 million was raised from the issue of 16 million shares, the Board of Directors made a bonus issue of 2 for 5 options held by shareholders on 5 March 2001. These options may be exercised at $0.75c and expire on 6 March 2006.

VRI BioMedical's primary objective is to create shareholder wealth. We will achieve this by commercialising our disease management products through on-licensing to other organisations that are best placed to exploit global market opportunities.

VRI BioMedical's dynamic portfolio of projects is the result of excellent scientific research. Our products cover the prediction and prevention of disease related to the body's immune system and span the major health care areas of disease management including cardiovascular, cancer, allergy and gastro-intestinal dysfunction.

The Company's products are at the forefront of a convergence that is taking place between chemistry and biology, prescriptive and "over the counter" medicines and the food and pharmaceutical industries.

Of particular interest is the emergence of our cardiovascular projects and diagnostics for coronary heart disease, Secril-4 Alert and Atheromastat. These projects are based on sound scientific research and compelling data and have emerged as flagship projects since the Company listed on the ASX.

Our ability to build upon research and development advances will contribute substantially to VRI BioMedical's growth. The completion of our commercial collaboration agreement with DSM of The Netherlands is an example of our strength in this area and marked a significant milestone in the early commercialisation program of the Company.

VRI BioMedical's science in the diagnosis and management of mucosal dysfunction is well advanced. We have a sound platform from which major commercial products can be brought to market and our marketing and commercialisation program is very active. We will maintain and develop relationships and continue open discussions with several large overseas pharmaceutical organizations to achieve successful commercialisation agreements.

Your Board of Directors, Executives and staff are dedicated to the aims and objectives of the Company. These people are highly talented, motivated, are experts in their respective fields and are focused on achieving positive outcomes and wealth creation for shareholders.

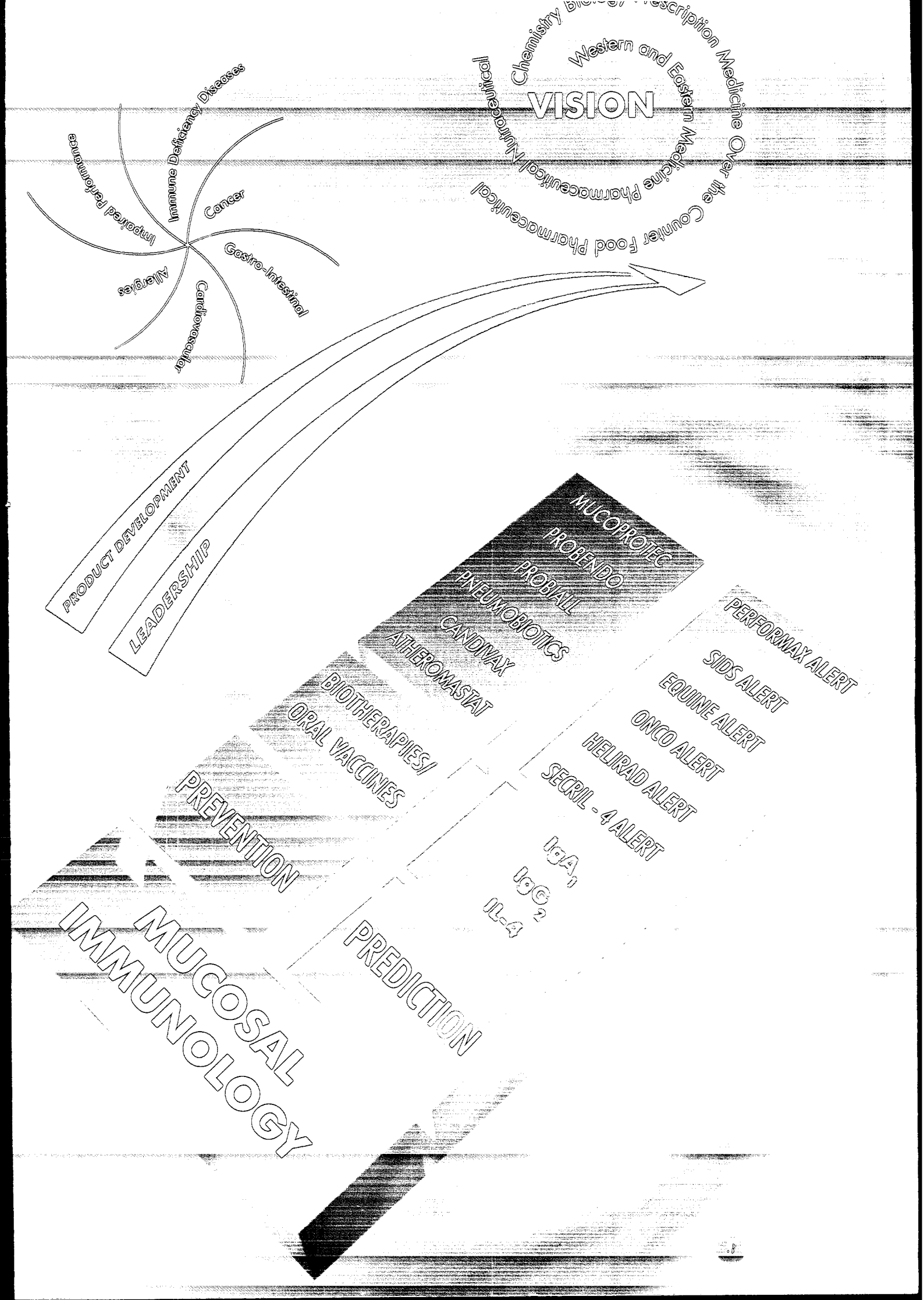
The appointment of London based Professor Glyn Tonge in September gives the Board additional strength in overseas capital markets and commercialisation strategies. Anthony Barton, a founding shareholder and director, retired from the Board in September 2001. I would like to thank him for his skills and guidance in the IPO and post listing strategies.

The excellent progress achieved over the past year is a result of the hard work and determination of all staff, consultants and Directors and I thank them all for their contributions.

We have entered an exciting era of new medical discovery. Your Company has world-class intellectual property, comparative and competitive advantages and is positioning itself to maximise the commercial opportunities of our projects and products in the future.

I look forward to another year of continued achievements for VRI BioMedical.

Leon Ivory
Chairman

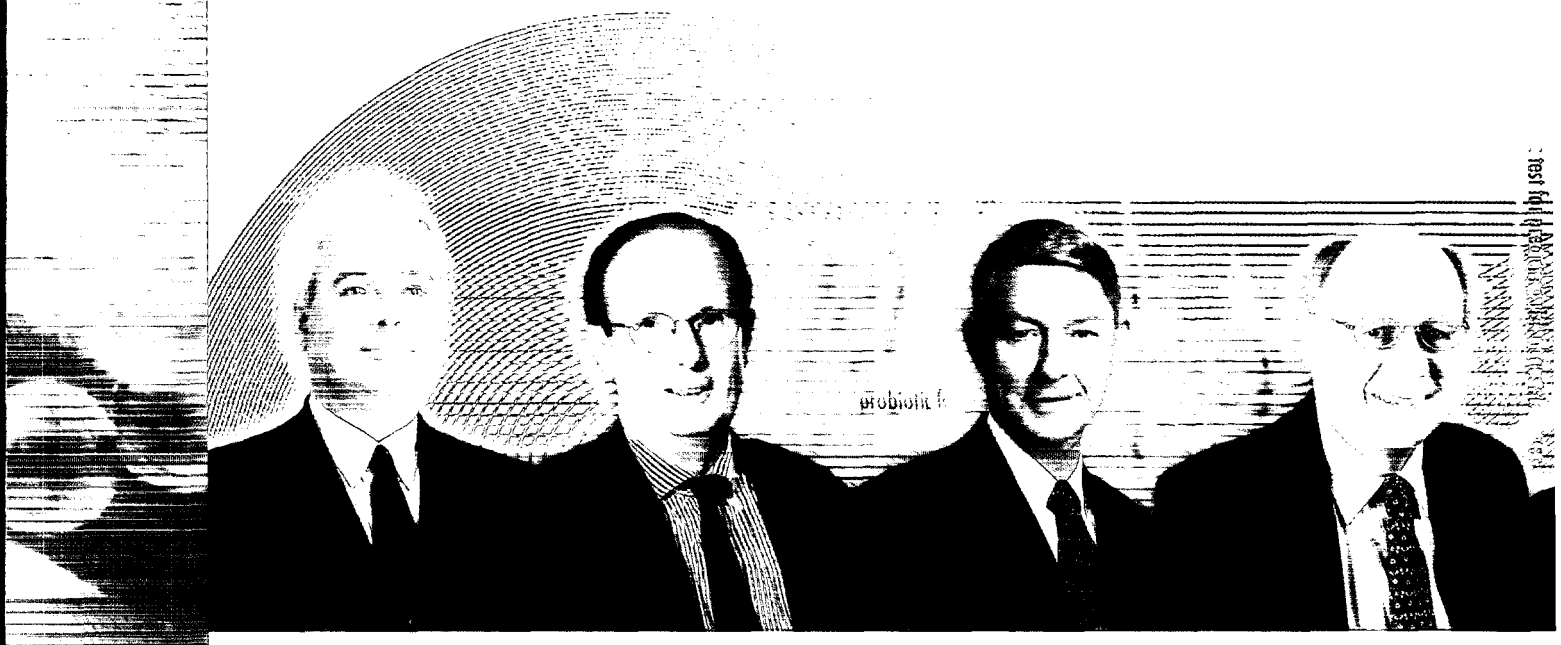

VISION
Chemistry Biology Prescription Medicine Over the Counter Food Pharmaceutical
Western and Eastern Medicine Pharmaceutical/Nutraceutical
Immune Deficiency Diseases
Cancer
Gastro-Intestinal
Cardiovascular
Allergies
Improved Performance
PRODUCT DEVELOPMENT
LEADERSHIP
MUCOPROTEC
PROBENDO
PROBIALL
PNEUMOBIOTICS
CANDIVAX
ATHEROMASTAT
BIOTHERAPIES/
ORAL VACCINES
PERFORMAX ALERT
SIDS ALERT
EQUINE ALERT
ONCO ALERT
HELIRAD ALERT
SECRIL - 4 ALERT
IgA1
IgG2
IL-4
PREVENTION
PREDICTION
MUCOSAL IMMUNOLOGY

# Directors' Report

Your directors submit their report for the year ended 30 June 2001.

## DIRECTORS

The names and details of the directors of the company in office during the financial year and at the date of this report are:



*Leon Ivory* *Kenneth Peter Baxter* *Professor Jack Cade* *Professor Robert Llewellyn Clancy*

**Leon Ivory**
**Chairman**
**Chief Executive Officer**

Leon Ivory is a graduate of the Advanced Management Programme of the University of Hawaii Business School and a Fellow of the Australian Institute of Management. Leon as founder of VRI BioMedical Limited, has been involved in corporate finance, funds management and venture capital in a career spanning over 30 years and he has served as a director of a number of public companies including Auspharm International Limited, Cortecs Plc, Arbuthnot Latham Bank Ltd (London), Foreign Commerce Bank (Zurich) and Australian Heritage Group Limited.

**Kenneth Peter Baxter**
**Non-Executive Director**
**B. Ec, FAIM, FAICA**

Ken Baxter is currently senior policy advisor on public sector reform to the Chief Secretary of Government in Papua New Guinea. He is an Adjunct Professor, Public Policy and Administration, University of NSW. Formerly secretary of the Department of Premier and Cabinet in Victoria and the Director General of the NSW Premier's Department, as well as director of other Public Companies. Appointed as Director on 1st November 2000.

**Professor Jack Cade**
**Non-Executive Director**
**MD, PhD, FRACP, FANZCA, FCCP**

Professor Cade is the inaugural director of Intensive Care at the Royal Melbourne Hospital for over 20 years. He is a leader in the development of intensive care medicine in Australia. His academic interests have been in thromboembolism, biomedical engineering, infections and ethics. Appointed as Director on 1st November 2000.

*Kim Robert Slatyer* *Professor Glyn Michael Tonge*

**Professor Robert Llewellyn Clancy**
**Non-Executive Director**
**B.Sc (Med), MBBS, PhD, FRACP, FRCP(C), FRCP**

Professor Clancy, as co-founder of VRI BioMedical Limited, is a clinical immunologist involved in the development of diagnostics therapeutic vaccines. He was a founding Board member of Auspharm International Ltd and was the Director of the Australian Institute of Mucosal Immunology. Professor Clancy is currently the Foundation Professor of Pathology at the University of Newcastle and Director of the Hunter Immunology Unit. He resigned as a Director of TUNRA Ltd on 29th May 2001.

**Kim Robert Slatyer**
**Non-Executive Director**

Kim Slatyer is a venture capitalist based in Western Australia. His current major project is the development of a new town at Vasse in South Western Australia through which he has interests in health-care, education, venture capital and property development. He is a co-founder of the Company.

**Professor Glyn Michael Tonge**
**Non-Executive Director**
**B.Sc(Hons) Biochemistry**
**PhD, C Biol, FIBiol, FRSA**

Professor Tonge is a visiting Professor of Biotechnology at the University of Bath and serves on a number of government committees advising on research in the biological sciences. He has held directorships with Baring Brothers & Co. Ltd, Baring Brothers International Ltd and ING Barings. Earlier in his career he held a senior executive position with ICI (now Astra Zeneca). His time with PA Consulting Group saw him develop its biotechnology and pharmaceutical business. He holds directorships with a large number of UK companies including Laxdale Ltd, eCare International Ltd, Site Intelligence Ltd, Penn Pharmaceuticals Ltd, Fraser Williams Plc and the Southampton Institute. Professor Tonge is currently a non-executive director of Dabur Oncology Plc, a UK pharmaceutical company specialising in Oncology with research and development in both the UK and India. Appointed as Director on the 10th September 2001.

**Anthony Peter Barton**
**Non-Executive Director**
**B. Bus Studies**

Anthony Barton has 21 years of commercial experience having acted in senior executive capacities of two leading Australian sharebroking firms and has extensive knowledge of the requirements for fundraising and listing on the Australian Stock Exchange. He is the Executive Chairman and the major shareholder of Australian Heritage Group Ltd, the largest shareholder of VRI BioMedical Limited.
Resigned as Director on 10 September, 2001.

The following summarises significant events in the origins and history of the Company and its existing projects:

1973

**1973 Discovery of common mucosal system by McMaster University Research Group in Canada.**

**1973 to 1999 Developed studies in relation to mucosal infection.**

**1973 to 1999 Development of "rules" for oral immunization in man.**
Developed animal models to define "proof of concept".

**1985 Oral therapeutic vaccine against recurrent acute bronchitis developed by Prof. Clancy's University of Newcastle research team.** (sold to Multi-national)

**1987 Collaboration on first H. pylori Laboratory diagnostic** (sold to Multi-national)

**1993 First commercial "near patient" diagnostic developed for H. Pylori infection.**
(licenced to Multi-national organisations world-wide)

**2000 VRI BioMedical formed - Leon Ivory, Kim Slayter & Prof. Clancy founders.**

**1999 Established relationship with the University of Newcastle and TUNRA.**

**1999 to 2000 Provisional patents and patent applications.**
VRI BioMedical filed ten patent and provisional patent applications in relation to its projects.

**2000 Cardiovascular projects set up**

**2000 $2.4 million raised from 'seed' capital investors.**

**2000 Exclusive license agreements for commercialisation of PerformaxAlert and SIDSAlert projects secured from TUNRA. Also concluded a comprehensive services agreement with TUNRA.**

2000

2000 **VRI BioMedical raises $12 million from the issue of 16 million shares at $0.75¢ each.**

**VRI BioMedical is listed on the ASX.**
The Company was accepted on the official list of the Australian Stock Exchange in December 2000

2000 **Provisional Patents lodged for Atheromastat and Equine Alert.**
VRI BioMedical lodged two provisional patents for...
- Methods for *predicting impaired performance in equines.*
- *Compositions and methods for diagnostics and treatment of cardiovascular disorders.*

**Agreement with TUNRA on Equine Alert.**
VRI BioMedical executed an agreement with TUNRA that secures the sole & exclusive ownership of Equine Alert.

2001 **2 for 5 Bonus Issue of options announced.**
23,377,733 options were allotted with a 5 year expiry and an exercise price of $0.75¢ per option.

**VRI BioMedical lodged a provisional patent for Secril 4 Alert**
Cytokine Capture Assay Methods and Uses.

2001 **Operations in Sydney commenced when VRI BioMedical opened two operational centers in Sydney.**

2001 **In June, Human Clinical Trial program commences.**
Ethics Committee approvals granted for 4 clinical trials
- *Mucoprotec MP1*
- *Mucoprotec MP2*
- *Probiall*
- *Probendo*

**In June Ethics Committee approval granted for trials in Equine Alert**

**Concluded Collaborative Research, Development and Commercialisation Agreement with DSM based in The Netherlands.**

2002

# Directors' Report

**Interests in the shares and options of the company and related bodies corporate**

As at the date of this report, the interests of the directors directly or indirectly in the shares and options of VRI BioMedical Limited were:

| Director | Number of Shares | Class | Options over Ordinary Shares |
|---|---|---|---|
| L Ivory | 9,000,000 | Ordinary | 3,600,001 |
| KR Slatyer | 9,000,000 | Ordinary | 3,600,001 |
| RL Clancy | 9,000,000 | Ordinary | 3,600,001 |
| KP Baxter | 11,500 | Ordinary | 20,800 |
| JF Cade | 268,100 | Ordinary | 107,240 |

L Ivory holds his shares through Ivory & Company Pty Ltd as trustee for The Ivory Trust.
KR Slatyer holds his shares through Trivenia Pty Ltd as trustee for The Kim Slatyer Trust.
RL Clancy holds his shares through Maktram Pty Ltd.
KP Baxter holds 2,500 of his shares and 7,200 share options through Baxter and Associates Pty Ltd

**Earnings per share**

Basic earnings per share - (6.10) cents

**Dividends**

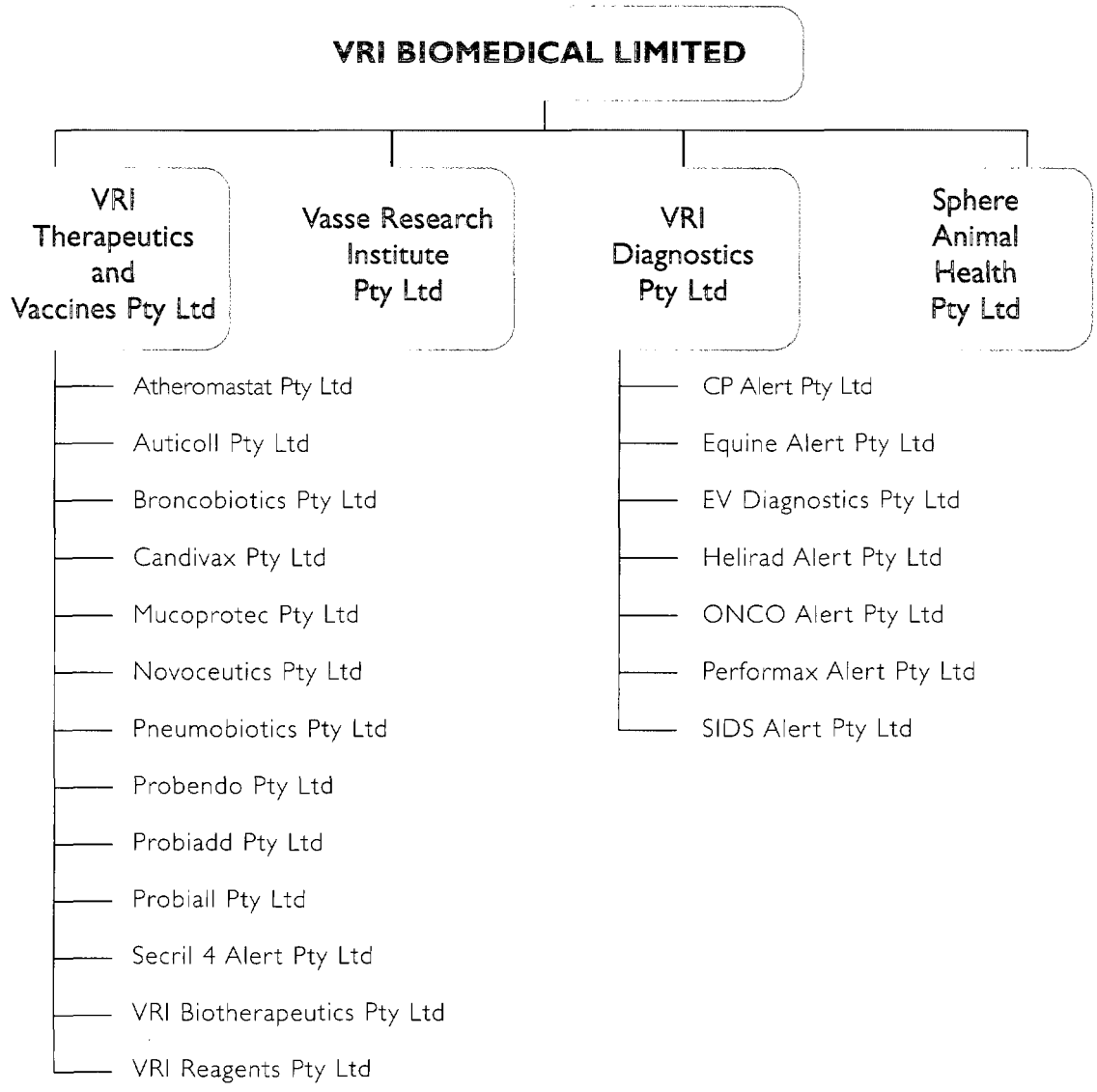
No dividends have been paid or have been recommended during the year.

# Directors' Report

## Corporate Structure

VRI BioMedical Limited is a company limited by shares that is incorporated and domiciled in Australia.

It is the ultimate parent entity and has prepared a consolidated financial report incorporating the entities that it controlled during the financial year, which are outlined in the following illustration of the groups corporate structure:



# Directors' Report

## Principal Activities

The principal activity of the Company is the research and development of products for the prediction and prevention of disease and health conditions essentially in the field of mucosal immunology (the immune system).

## Employees

The consolidated entity employed 18 employees as at 30 June 2001 (2000: nil employees).

## Review and Results of Operations

The 12 months to 30th June 2001 witnessed positive transition for VRI BioMedical. The Directors, Executives and staff of the Company achieved considerable milestones during this period from

- the on-going development of the Company's Intellectual Property and patent portfolio,
- continuing scientific innovation,
- moving projects from Research into Development phases,
- progression of provisional patents to patent co-operation treaty (PCT) phase,
- raising adequate capital from pre-IPO "seed" investors and from an Australian IPO,
- ethics committee approvals for many human and animal study trials some in Phase II, and
- early execution of the international commercialisation programme.

### Initial Public Offering (IPO)

The Company moved from an unlisted to a listed Australian public entity. Its IPO in December 2000 was oversubscribed. $12 million was raised from the allotment of 16 million shares at $0.75c each. This followed the pre-IPO capital raising of $2.4 million earlier in the year.

This capital gave funding certainty for a 3-year research and development programme as outlined in the Prospectus to develop products that have global application.

Additionally, 2 for 5 bonus options were issued to shareholders early in 2001 that raised contingent capital of $17.5 million. 23,377,733 options were allotted. These options, may be exercised at $0.75c on or before 6th March 2006.

### Intellectual Property/Patent Portfolio

*Profound Intellectual Property has been captured through innovative scientific research in areas* across the Company's science platforms of *Prediction* and *Prevention*. The products cover the large global health areas of cardiovascular diseases, gastro-intestinal diseases and cancer.

The Company's cutting-edge science reflects a paradigm shift in medical thinking and understanding related to the body's immune system – the front line of defence against disease. It builds on the vast international experience of the Company's scientific team in the areas of mucosal immunology and bio-therapeutics.

# Directors' Report

## Review and Results of Operations (continued)

The projects that form part of the Company's ***Prediction*** platform focus on technology that can alert clinicians to the onset or existence of certain medical conditions. These products all have global application in huge market segments. Being essentially non-invasive they have a lower regulatory hurdle with early-to-market potential.

Projects that form the Company's **Prevention** science platform are those in bio-therapeutics and probiotic vaccines. They too have global application in large market segments. Many of these projects have moved from research phase into product development including ethics approvals for human clinical trials in some instances.

During the year under review, the following provisional patents were lodged:

- **A probiotic preparation to control endotoxaemia and its complications in acute and chronic circumstances (Probendo Project)**

This project aims at minimising transposition across the gut mucosa by gram-negative bacteria under circumstances of impaired mucosal function as occurs when blood perfusion is altered or excess alcohol is ingested. This leads to high levels of circulating endotoxin that, in an acute situation, can cause shock and severe systemic disease. In more chronic situations it contributes to progressive liver cell damage and cirrhosis of the liver.

The probiotic reduces endotoxin levels and liver cell necrosis in an animal model of alcohol-related liver disease. Studies in man will examine models of post-operative endotoxemia and chronic alcohol liver disease to obtain proof-of-concept of value in these acute and chronic examples of endotoxin related tissue damage.

- **A quantitative test using saliva to detect a failure to respond to H. pylori eradication therapy (Helirad Alert Project)**

Scientific research suggested that saliva antibody levels rapidly fell following effective eradication therapy for *H. pylori*. This observation suggested an opportunity to develop a much-needed non-invasive method of demonstrating effective eradication, without the expensive or invasive technology that currently exists. Ten percent to 30% of subjects currently fail to eradicate *H. pylori* following the first course of antibiotics – these subjects need to be identified.

VRI BioMedical developed technology that maintains antibody stability and has demonstrated a rapid response of antibody in subjects having effective eradication.

- **A rapid quantitative assay of IgA1 in saliva to monitor performance capacity in horses (Equine Alert Project)**

EquineAlert is a similar test to PerformaxAlert which has been adapted for determination of overtraining/impaired performance and fatigue in thoroughbred horses. It also measures IgA in saliva.

# Directors' Report

## Review and Results of Operations (continued)

There have been no studies, to the best of our knowledge, in any animal model, to develop an assay to monitor fatigue.

Extensive field testing under Animal Ethics Committee approval is underway with positive preliminary results emerging.

- **Compositions and methods for diagnosis and treatment of cardiovascular disorders. (Atheromastat Project).**

Coronary artery disease and more specifically atheroma, which is the formation of obstructions or plaques in the arteries of the heart, is the most common cause of death in the western world.

The Atheromastat project is developing a diagnostic test to detect the presence of atheroma plaque. This test is less invasive and more cost effective than current medical procedures.

This project was moved from the VRI BioMedical incubator programme to an active status following the successful completion of further human testing in excess of 150 people to-date.

- **Cytokine Capture Assay Methods and Uses. (Secril 4 Alert Project).**

In recent times, the measurement of cytokines as a monitor of human disease has rapidly gained in medical interest. However, to-date it has remained only a research tool as a measure of T lymphocyte function.

T cells are the directors of the immune system. They do so by releasing messenger molecules (cytokines) that tell other cells what type of response to make. Measurement of particular cytokines can be indicative of certain disease states.

The Company is developing its Secril 4 Alert technology for widespread clinical use in the diagnosis and prediction of immune related disorders.

The invention relates to methods of detecting and quantitating cytokine levels by a unique in situ capture technique. The invention also relates to measurement of cytokine in combination with other markers of T cell response.

- **Methods for predicting impaired performance in Equines. (Equine Alert Project).**

Following successful research results, an additional provisional patent was lodged in the latter half of 2000 that attended to the bio-therapeutic treatment of equines to enhance their immune system against disease.

# Directors' Report

## Review and Results of Operations (continued)

The Company's intellectual property and patent portfolio is regarded as its most valuable asset. Management continually focuses on this issue and utilises the expertise of highly regarded Patent Attorneys, Baldwin Shelston Waters, to actively assist in the on-going management of this asset base.

During the financial year, many provisional patents were progressed to PCT applications. The licenced-in patent for Performax Alert migrated to its National Phase filing at the date of this report.

The Company's patent portfolio is shown in the table below:

| Project | Title | Status |
|---|---|---|
| Performax Alert | Method for determining predisposition to infection | Entered National Phase in August 2001 |
| ONCO Alert | Methods for preventing and/or diagnosing the risk of gastric cancer | National Phase due November 2001 |
| SIDS Alert | A method of determining potential susceptibility to development of ALTE and/or SIDS | National Phase due December 2001 |
| ProbiaII | Compositions and methods for treatment of allergic disorders | International Preliminary Examination demand filed |
| Candivax | Composition and methods for treatment of candidiasis | PCT filed |
| Mucoprotec / Probiaid | Compositions and methods for immunotherapy/eradication of H.pylori infection | PCT filed |
| Helirad Alert | Methods for monitoring treatment of helicobacter infection | PCT filed |
| Probendo | A method of treating endotoxaemia | PCT filed |
| Equine Alert | Methods for predicting impaired performance in equines | PCT filed |
| Atheromastat | Compositions and methods for diagnosis and treatment of cardiovascular disorders | Provisional application |
| Secril 4 Alert | Cytokine capture assay methods and uses | Provisional application |
| Broncobiotics | Compositions and methods for non specific immunotherapy | Provisional application |

# Directors' Report

## Review and Results of Operations (continued)

## Project Review

Four initial objectives following the IPO in December 2000 were:

- To consolidate intellectual property and move patents into the PCT phase. This involved further research and testing to accumulate appropriate scientific data to support the proper filing of the patent programme.
- To gain ethics committee approval for bio-therapeutic trials.
  There are now five ethics committee approvals. One trial has begun with one more expected to start later in 2001. Obtaining an ethics committee clearance for a clinical trial is a major milestone for a biotechnology company, as it represents an achievement in obtaining quality material, good proposal presentation and accepted science.
- To conclude an agreement with a major fermentation facility to partner product selection and production.
  This was achieved with the recently signed agreement with a predominant multi-national company, DSM. This is a major milestone for VRI providing the enabling technology essential for bio-therapeutic product development. The new isolate project that is the corner stone of this agreement is now underway.
- To advance technology agreements with companies, which possess vehicles for the innovative diagnostics developed by VRI.

The company has a range of projects under development clustered into prediction and prevention within three platforms, namely diagnostics, biotherapeutics and oral vaccines.

## Prediction

### Diagnostic Tests

An enormous wealth of information regarding the type and progress of diseases can be determined by the measurement of various factors involved in the immune response. VRI diagnostics are based on this principle and are predictive of a number of different diseases and conditions.

### Secril 4 Alert:

- Secril 4 Alert is an effective, reliable and inexpensive method for measuring a specific cytokine (local intracellular messenger) in biological fluids.
- VRI has shown that this cytokine is a strong biological marker for a range of diseases and conditions such as coronary heart disease, *H. pylori* infection and eradication, gastric cancer and allergy.

# Directors' Report

## Project Review (continued)

### Prediction (continued)

- Outcomes from initial human studies support the use of Secril 4 Alert to:
  - Determine atherosclerotic load in patients suffering from coronary heart disease (CHD). CHD is the most common cause of death in the western world[1] and is estimated to cost the USA alone US$100 billion per annum.[2]
  - Predict who will and who will not respond to short term *H. pylori* eradication therapy. Approximately two-thirds of the world's population is infected with H. pylori, which is estimated to be the primary cause of 80% of peptic and 90% of duodenal ulcers [3].
  - Predict the likelihood of precancerous lesions and gastric cancer. H. pylori causes over half the cases of gastric cancer[4] a condition that is the second leading causing of cancer related mortality worldwide with some 368,000 deaths per year in China alone[1].
  - Improve the use of desensitisation therapy in the ongoing management of allergy. Allergy affects upwards of 20% of the adult population[5], while asthma is believed to affect 11% of the Australian population[6].
- Human clinical trials are ongoing.

#### Helirad Alert

- Helirad Alert is a method of determining success or failure of *H. pylori* eradication therapy by measuring antibody levels in saliva.
- Infection with *H. pylori* produces a strong specific antibody response.
- VRI has shown that following eradication salivary antibody levels fall much faster compared to antibody levels in the blood (same level of antibody after 6 weeks post-treatment in saliva compared to 6 months in blood).
- Helirad Alert will monitor the outcome of *H. pylori* eradication by measuring changes in *H. pylori* specific antibody.

#### ONCO Alert

- ONCO Alert will be a non-invasive measure of *H. pylori* specific antibody to determine the risk of gastric cancer.
- *H. pylori* has been shown to cause over half the cases of gastric cancer in the world[4] and there is an estimated worldwide burden of almost half a million new cases of gastric cancer annually attributable to *H. pylori*[7].
- Unfortunately due to a lack of effective diagnostic screening tools, gastric cancer is usually identified at an advanced stage with a poor prognosis (15%, 5 years after diagnosis)[4].
- In human studies completed by VRI, pre-cancerous patients with *H. pylori* infection were found to have low specific antibody levels and these levels were even lower in patients with gastric cancer.
- Based on these findings ONCO Alert will measure specific antibody levels to determine a patient's risk of having or developing gastric cancer.

---

[1] World Health Organization (WHO). The World Health Report 1999: Making a Difference. WHO, Geneva.
[2] American Heart Association. 2001 Heart and Stroke Statistical Update. Dallas, Texas: American Heart Association, 2000.
[3] Centre for Disease Control & Prevention. H. pylori Fact Sheet for Health Care Providers. Atlanta, GA, USA.
[4] Forman D (1998). Helicobacter pylori infection and cancer. Br. Med. Bull. 54(1), pp.71-78.
[5] American Academy of Allergy, Asthma and Immunology. Task Force on Allergic Disorders. Executive Summary Report. (1998).
[6] Mathers C, Vos T, Stevenson, C 1999. The burden of disease and injury in Australia. AIHW cat. no. PHE 17. Canberra: AIHW.
[7] Pisani P et al. (1990). Cancer and infection: estimates of the attributable fraction in 1990. Cancer Epidemiol. Biomarkers Prev., 6, pp. 387-400. As cited in Forman D (1998). Helicobacter pylori infection and cancer. Br. Med. Bull. 54(1), pp.71-78.

# Directors' Report

## Project Review (continued)

### Prediction (continued)

#### Performax Alert

- Performax Alert is a method of determining the predisposition to infection in a subject exposed to various stressors by measuring levels of antibodies in saliva.
- VRI together with the University of Newcastle and the Australian Institute of Sport (AIS) have shown that elite athletes have suppressed antibody production after exercise and increased susceptibility to respiratory infection, which in turn may lead to performance decline.
- VRI believes these effects may be due to changes in the athletes immune capability and reactivation of previously dormant Epstein-Barr virus (EBV). EBV affects more than 90% of adults in western countries and is a common cause of viral illness in exercising people, although over 50% of the primary infections are asymptomatic[8].
- VRI has shown that immediately after exercise there is a disturbance of normal immune parameters that can last for some hours[9]. Intense exercise therefore has the potential to reduce normal immune control of the EBV virus, allowing it to reactivate, shed into saliva and cause respiratory illness and performance decline.
- Field studies in collaboration with the AIS are ongoing.

#### SIDS Alert

- SIDS Alert is a diagnostic test to measure specific antibody levels and predict whether a baby is at risk of developing SIDS.
- The incidence of SIDS in western countries has fallen from 2 per 1000 live births to around 0.8 per 1000 live births[10]. However, these figures mean that approximately 200 babies in Australia and 5,600 in the USA still die from SIDS each year.
- The Mucosal Group at the University of Newcastle found an abnormal increase in antibody levels within the saliva of a baby who died from SIDS[11].
- A subsequent study of infants who recovered from unexplained apnoea (known as Acute Life Threatening Events or ALTE's) showed that the same antibody was the most defining molecule.
- VRI has exclusive rights to the patent from the University of Newcastle.

#### Equine Alert

- Equine Alert will measure the competence of the mucosal immune system and predict performance decline in racehorses.
- Racehorses are exposed to severe training/exercise and competitive stress and respiratory infection with herpes-type viruses is common and has been shown to adversely affect performance[12].
- In 1998/1999 AUD$154 billion was bet on horseracing, harness racing and greyhounds (the overwhelming majority on horseracing) with the most bet in Japan, the USA, Hong Kong and Britain.[27]

---

[8] Peters EM & Bateman ED (1997). Immunology and upper respiratory tract infections. Int. J. Sports Med. 18, S69-S77.
[9] Gleeson M. (2000). Mucosal immune responses and risk of respiratory illness in elite athletes. Exercise Immunol. Rev., 6, pp. 5-42.
[10] The Management of Sudden Infant Death– A Guide for General Practitioners. SIDS Australia. (www.sidsaustralia.org.au)
[11] Gleeson M, Clancy RL, Cripps AW. (1993) Mucosal immune response in a case of sudden infant death syndrome. Pediatr Res. Jun;33(6), pp. 554-556.
[12] Wilcox GE & Raidal S (2000). Role of viruses in respiratory disease. A report for the Rural Industries Research and Development Corporation. Publication No. 00/146, ACT, Australia.

# Directors' Report

## Project Review (continued)

### Prediction (continued)

- VRI has completed several field studies with Equine Alert in some of the most well known stables in Australia. Results from these studies have been encouraging, showing that:
  - o Salivary IgA can be effectively sampled and measured in racehorses;
  - o Levels of salivary IgA can vary markedly between individual animals;
  - o There appears to be a good correlation between salivary IgA levels and performance as determined by the horses' trainer, especially when measured across a training period.
- Analysis of data is ongoing.

### Prevention

#### Biotherapeutics

VRI is developing a range of products based on the ability of certain bacteria to boost the host's immune response to infection and disease. These are called biotherapeutics. Importantly bacteria must be delivered to the small intestine alive, metabolically active and in sufficient numbers[13]. VRI has shown that only specific strains of bacteria will provide these benefits.

#### Probiall

- Probiall is a particular high dose biotherapeutic given in a proprietary formulation (to ensure delivery of sufficient live bacteria) that will alter the inappropriate immune response in allergy and asthma patients.
- In the USA nearly 36 million people suffer from seasonal rhinitis, which cost the community an estimated US$3.4 billion in 1993[14], while nearly 15 million Americans were estimated to suffer from asthma in 1996[15] which cost the USA a total of US$12.6 billion. Other western countries show similar figures relative to their population size.
- VRI has shown in animal models that Probiall will alter the immune parameters that lead to allergic reaction and aid in the production of a "normal" response to challenge by allergic triggers.
- Trials in human subjects using Probiall in combination with desensitisation therapy are due to commence shortly.

#### Probiaid

- Probiaid is a particular biotherapeutic given at high doses in a proprietary formulation that will optimise *H. pylori* eradication therapy.
- Combination eradication therapy cost Australia AUD$10 million in 1998[16], which translates to an estimated AUD$1 billion worldwide each year.

[13] Conway P. (1996). Selection criteria for probiotic microorganisms. Asia Pacific J. Clin. Nutr. 5, pp. 10-14.
[14] American Academy of Allergy, Asthma and Immunology. Statistics on Asthma and Allergic Disease. (www.aaaai.org).
[15] Vital and Health Statistics Series 10, No. 200. US Centers for Disease Control & Prevention.
[16] Australian Statistics on Medicines 1998. Commonwealth Department of Health and Aged Care.

# Directors' Report

## Project Review (continued)

### Prevention (continued)

#### Probiaid (continued)

- Human studies conducted by VRI have shown that in order to eradicate the organism both the eradication therapy and an efficient host immune response are required.
- VRI believes that Probiaid will optimise the host immune response, thus maximising the potential effect of the eradication therapy.

#### Probendo

- Probendo is a particular high dose biotherapeutic given in a proprietary formulation that will reduce blood endotoxin levels to reduce and/or eliminate the complications of endotoxaemia.
- Endotoxaemia, resulting from excess release of toxins by certain microbes (especially *E. coli*) or post-surgical complications, causes fever, liver damage, changes to the pattern of blood cells and can lead to life-threatening, irreversible haemorrhagic shock.
- In animal models of endotoxaemia VRI has shown that administration of Probendo reduced the levels of markers of liver cell damage.
- Planning for Clinical trials in humans is underway with human ethics committee approval being granted. In these studies patients preparing for open-heart surgery are to be pre-treated with Probendo to up-regulate their immune system.

#### Mucoprotec

- Mucoprotec is a particular biotherapeutic given at high doses in a proprietary formulation that will non-specifically activate the mucosal immune system.
- VRI has shown in animal models that regular delivery of probiotics will prime immune cells to respond vigorously and quickly to challenge, thereby preventing infection or viral reactivation.
- Oral thrush is a common problem in the elderly, particularly those with dental prostheses (4% of people with full dentures), HIV patients (upwards of 93%) and those taking inhaled steroids[17]. Recurrent vaginal thrush affects 5% of women[18], with an estimated 13 million cases each year in the USA[19].
- In an animal model of oral thrush, Mucoprotec was found to produce a more pronounced immune response after infection by *Candida albicans* and to accelerate the removal of the yeast from the body.
- VRI believes that Mucoprotec will be an effective therapy to protect patients from recurrent infections such as denture related oral thrush. It will also limit the duration and intensity of recurrent vaginal thrush.
- Priming the immune system using Mucoprotec should also maximise mucosal fitness in athletes by optimising their immune response, thereby reducing the risk of respiratory illness and performance decline.
- Planning for two human clinical trials have commenced with human ethics committee approvals being granted.

[17] "Oral Health in America: A Report of the Surgeon General". Rockville, MD: U.S. Dept of Health and Human Services, National Institute of Dental and Craniofacial Research, National Institutes of Health, 2000.
[18] Carcio & Secor 1992. Vulvo-vaginal candidiasis: A current update. Nurse Practitioner Forum 3(3) pp135-144. As cited in "Kidney & Urinary Tract Diseases & Disorders Sourcebook." Edited by Linda M. Ross. Omnigraphics Inc. 1997.
[19] FDA Press Release 1992.

# Directors' Report

## Project Review (continued)

### Prevention (continued)

#### Oral Vaccines

Vaccines are innocuous forms of infectious organisms or their toxins that retain the ability to produce an immune response. The body will then produce a vigorous and highly specific response to the antigen should the antigen present again in the future.

#### Pneumobiotic

- Pneumobiotic will use the combined effectiveness of a killed vaccine with a biotherapeutic preparation capable of inducing an enhanced immune response to treat acute exacerbations of chronic bronchitis.
- Patients with chronic bronchitis commonly develop recurrent acute bronchitis, as a consequence of infection with certain bacteria[20,21].
- Smoking is the major risk factor for the development of this condition, with the risk of developing chronic bronchitis increasing proportionately with the number of packs smoked per year[22].
- Using international population[23] and tobacco usage[24] statistics there are an estimated 457 million smokers in 9 nations.
- Pre-clinical studies by VRI have shown that Pneumobiotic is effective in clearing the offending bacteria and the combination is more effective than the individual components.
- Clinical trials currently planned by VRI will determine the efficacy and safety of the vaccine in protecting chronic bronchitis patients from recurrent infectious episodes.

#### Candivax

- Candivax is an oral vaccine for long term prevention and/or treatment of numerous types of candida infection (thrush).
- Vulvovaginal candidiasis is the 2nd most common vaginal infection in the USA[25]. It was estimated that the incidence of vulvovaginal candidiasis doubled in 1981 and 1991[26].
- The frequency and severity of infection increases in immuno-compromised individuals, especially in pregnancy, diabetes, broad-spectrum antimicrobial use and corticosteroid use[26].
- VRI animal models have shown that immunisation with a specific form of *C. albicans* produced early onset and higher levels of immune factors correlating with lower levels of colonisation and faster clearance of *C. albicans*.
- Human clinical trials are planned.

---

[20] Wilson R (1998) The role of infection in COPD. Chest 113, pp. 2425-2485.
[21] Murphy TF (2000) Haemophilus influenzae in chronic bronchitis. Sem. Resp. Infect. 15, pp. 41-51.
[22] Cerveri I et al. for the European Community Respiratory Health Survey (ECRHS) Study Group (2001). Variations in the prevalence across countries of chronic bronchitis and smoking habits in young adults. Eur Respir J; Vol 18, pp. 85–92.
[23] U.S. Bureau of the Census, Report WP/98, World Population Profile: 1998, U.S. Government Printing Office, Washington, DC, 1999.
[24] Corrao MA, Guindon GE, Sharma N, Shokoohi DF (editors). Tobacco Control Country Profiles, American Cancer Society, Atlanta, GA.
[25] Sobel 1990 Obst. Gyn. Clin. of Nth Am. 17(4), pp. 851-879. As cited in "Kidney & Urinary Tract Diseases & Disorders Sourcebook." Edited by Linda M. Ross. Omnigraphics Inc. 1997.
[26] Kent H.L. Am. J. Obst. Gyn. 165(4), 1168-1176. As cited in "Kidney & Urinary Tract Diseases & Disorders Sourcebook." Edited by Linda M. Ross. Omnigraphics Inc. 1997.
[27] International Federation of Horse Racing Authorities – 34th Annual Conference.

# Directors' Report

## Project Review (continued)

VRI has secured prototype reader and ELISA technology for its diagnostic projects. Discussions are in place with two companies with unique laboratory and near subject technologies. Thus, the key enabling technologies needed to commercialise VRI diagnostic intellectual property is in place or near to completion.

Excellent progress has also been achieved in unique tablet formulation for the bio-therapeutic projects.

There has been a continuous review process with a grouping and alignment of diagnostics with therapeutics to streamline the product portfolio along more programmatic lines. This process has added significantly to an understanding of the science behind the products and resulted in a strengthening the patent portfolio.

Management continues to recognise the importance of remaining innovative. This is represented in the significant advances in the Intellectual Property portfolio of the Company this financial year.

The following table outlines the Company's active project portfolio at the time of this report:

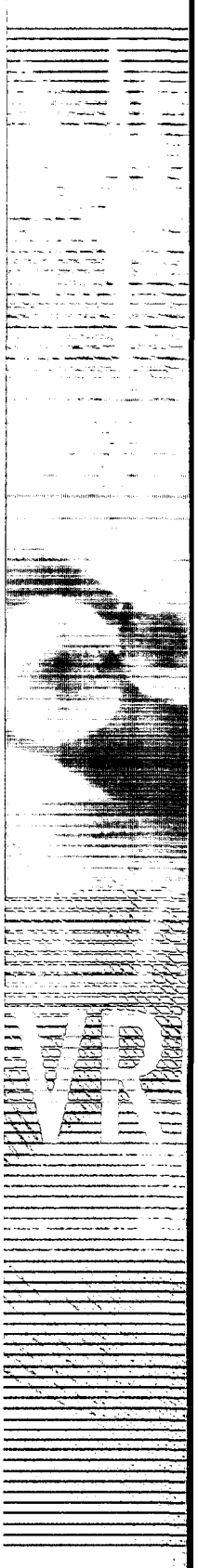
| Science Platforms | Prediction | Prevention | |
|---|---|---|---|
| | | Therapeutics | Vaccines |
| | Performax Alert | Mucoprotec | Pneumobiotics |
| | SIDS Alert | *Probiall* | Candivax |
| | ONCO Alert | Probendo | |
| | Helirad Alert | Probiaid | |
| | Equine Alert | Atheromastat | |
| | Secril 4 Alert | | |

The Company has an incubator programme in which projects are nurtured and which will allow a continuous flow of emerging products for the Company's sustainable viability. Of particular note is the Company's Animal Health projects that are being funded to develop Intellectual Property in diagnostics and bio-therapeutics in Equines and economic animals.

# Directors' Report

The following table summarises the current position of VRI product development:

| Product | Purpose | Outcome | Continuing |
|---|---|---|---|
| **IgA1 Saliva Assay**<br>a) Performax Alert<br><br>b) SIDS Alert | • To predict impaired performance<br><br>• To detect risk of SIDS | • Field trials continue<br>• Specifications for commercial assay complete and kits tested (same kit for both assays)<br>• Commercial discussions commenced | • Further field studies<br>• Near subject assay to be completed<br>• Expanding test population to shift workers<br>• Correlating with Biotherapeutic |
| **IgG2 Anti-*H.pylori* antibody**<br>a) ONCO Alert<br><br>b) Helirad Alert | • Blood test to detect risk of cancer<br><br>• Saliva test to detect successful treatment | • Specifications for commercial assay complete & test kits being produced (same kit for both assays)<br>• Field trials<br>• Commercial discussions commenced | • To continue field trials to determine value in China<br>• Near subject assay to be completed<br>• Correlating with Biotherapeutic |
| **IgA Saliva Assay**<br>Equine Alert | • To predict over-training & to manage training | • Four field trials complete<br>• Correlations between trainer & test<br>• Test predicts outcome of training programme | • Source a commercialisation partner<br>• Develop rapid assay<br>• Review need for further trials<br>• Correlating with Biotherapeutic |
| **L.acidophilus**<br>Mucoprotec | • To enhance mucosal immunity and prevent infection and allergy | • Ethics clearance and first two trials planned<br>• Intellectual Property expanded<br>• Co-link with Performax (above)<br>• Commenced commercial discussions | • Commercialising continuing<br>• Refined within DSM agreement (with additional IP & product lines)<br>• Increase in target populations<br>• Invited participation in large UK study (infants)<br>• Study in pregnancy – to reduce allergy in infants |



# Directors' Report

VRI product development (continued)

| Product | Purpose | Outcome | Continuing |
|---|---|---|---|
| **L.acidophilus** Probiall | • To downregulate allergy (co-link with desensitisation) | • Ethics clearance & trial to commence with injection desensitisation<br>• Invited for study in UK | • Trials discussed in Germany |
| **L.acidophilus** Probendo | • To reduce endotoxaemia<br>– acute<br>– chronic | • Ethics committee clearance<br>• View IP<br>• Linkage with Performax | • Trials to begins when Mucoprotec study finalised |
| ***Oral Vaccines***<br>a) Pneumobiotics<br><br>b) Candivax | • To reduce recurrent bronchitis in airways disease<br><br>• To reduce recurrent mucosal thrush | • Candidate vaccine selection begun<br>• Lactobacillus/killed bacteria formulation begun<br>• Advanced co-development discussions (Pneumobiotic)<br>• IP & quality laboratory data for Candivax<br>• Commercial negations underway regarding Pneumobiotics project | • Complete pre-clinical with Phase I study in 2002 (Pneumobiotic)<br>• Pre-clinical studies completed re Candivax |
| ***Secreted IL-4 capture assay*** Secril 4 Alert | To assess T cell response in host parasite relationships (First clinically valuable cytokine assay) | • Specifications complete & kits constructed<br>• Important clinical value defined<br>– *measure degree of coronary heart disease*<br>– detect those who fail to respond to *H.pylori* treatment | • Field trial of kits<br>• Explore additional uses especially to monitor allergy treatment (link with Probiall)<br>• Source commercialisation partner. |

# Directors' Report

## Clinical Trials

During the second half of the financial year the Company activated its clinical trial programme. Appropriate expertise was sourced to manage and run a tight clinical trial unit and several applications were submitted to ethics committees for trials in humans and animals.

During 2001 the Company has received five Ethics Committee approvals to commence clinical trials in humans and equines.

These human trials represent considerable milestone events for the Company and the recognition of the relevant science having been proven in animal models.

These Ethics Committee approvals received were for the following projects:

- **Mucoprotec Project**

The Mucoprotec Project is developing a bio-therapeutic preparation to be taken orally to enhance resistance of mucosal surfaces (the immune system) to various infections.

The Mucoprotec Project is especially relevant given increasing medical concerns regarding the rapid global increase in drug-resistant bacteria. Some bacteria are developing resistance to existing drugs faster than potent alternatives are being developed. It is thus more important than ever for the human immune system to be as strong as possible.

Animal models conducted by VRI BioMedical have provided consistent data showing rapid and marked resolution of infection, suggesting this bio-therapeutic therapy restores high level of mucosal resistance (improved immune response) when it is impaired.

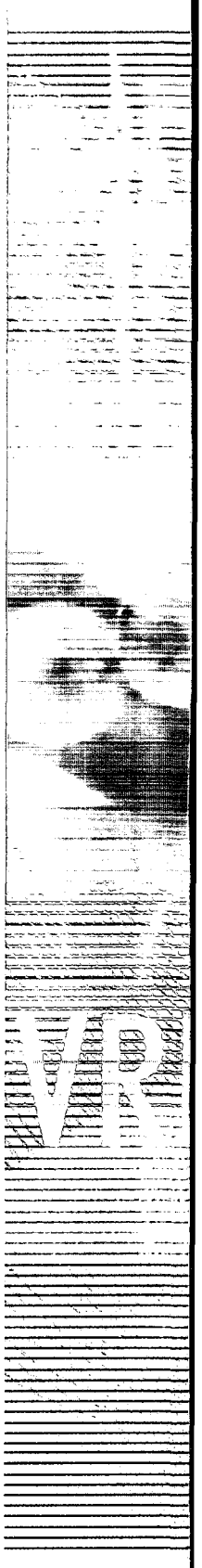
Two Human Research Ethics Committee approvals have been received by VRI BioMedical:

- **Mucoprotec MP-1 Human Trial – Newcastle**

Human Research Ethics Committee approval was received for testing in humans in 2001.

The trial is to determine the effect of regular intake of a bio-therapeutic preparation on human immunity and specifically that mucosal immune function is boosted. Improvement of general mucosal health benefits everyone, but in particular those who experience recurring infections, elderly people and any individual showing a decreased immune response.

The trial is a randomised, double blind controlled study and is scheduled to involve 50 subjects in two groups (25 per group).



# Directors' Report

## Clinical Trials (continued)

- **Mucoprotec MP-2 Human Trial – Canberra**

Human Research Ethics Committee has been received for a double blind, placebo controlled, paired clinical trial to determine the ability of bio-therapeutics to enhance immunity in elite athletes. The trial will be conducted at the Australian Institute of Sport in Canberra.

Work on developing a unique tablet formulation has been taking place by the Company's scientists, as well as the preparations needed to arrange and manage this human trial.

The trial that will involve 50 subjects in two groups (25 per group) is to determine the benefits of the VRI BioMedical bio-therapeutic product on elite athletes in increasing their mucosal heath in the gastrointestinal system.

- **Probiall Project Human Trial**

Human Research Ethics Committee approval has been received to commence a double blind, placebo controlled clinical trial to determine the ability of bio-therapeutics as an aid in desensitisation therapy against allergic reactions.

The VRI BioMedical Probiall Project focuses on developing a bio-therapeutic preparation to be taken orally to reduce the effect of allergic reactions in subjects prone to develop, or who have developed, allergic disease.

*Allergic reactions such as asthma, rhinitis and eczema are generally widespread affecting around 30 % of the world's population and gives rise to varying levels of discomfort and illness and the associated loss of quality of life and productivity.*

*Rhinitis can be classified into allergic and non-allergic forms, the former accounting for as many as 50% of patients presenting with chronic nasal symptoms.*

*Allergic airway diseases are increasing in prevalence and it is now appreciated that allergic rhinitis and allergic asthma commonly coexist. The prevalence of diagnosed allergic rhinitis (hay fever) among patients visiting general practitioners is between 11 and 20 per 1,000 in Western Europe, and 86 per 1,000 in Australia. These figures are underestimations, since they exclude those individuals not seeking medical help and those in whom the condition is unrecognised by the physician.*

*The prevalence of hay fever in the USA has been estimated at about 15% to 20% of population, or more than 40 million persons (10% of children, 20% of adults). Drugs for the treatment of "anti-allergic, non-asthma" diseases are estimated to have a worldwide market of between US$4 billion and $5 billion. The sales potential for an effective OTC product is, therefore, extremely high.*[1]

[1] David Randerson BE,Msc,PhD,FAICD.

# Directors' Report

## Clinical Trials (continued)

VRI BioMedical has shown in animal experiments that the use of certain bio-therapeutics have had a beneficial effect in decreasing allergic reaction. This human trial is to demonstrate that similar mechanisms of protection can be induced in humans.

The trial will involve two groups of subjects (30 per group) and will be conducted over an extended period.

- **EquineAlert Project**

The EquineAlert Project sets out to develop a rapid quantitative measurement using saliva to determine over-training / impaired performance and fatigue in thoroughbred horses.

Approval has been received from the Animal Care and Ethics Committee at the University of New South Wales for a study involving over 100 thoroughbred horses.

The full results from this study are expected to be available in the 4th quarter of 2001.

This study will involve measuring IgA and Herpes virus determination and leads to an oral bio-therapeutic trial to measure improved immune responses. The study will also involve biopsy tissue analysis.

Early indications form these trials are very encouraging.

*This product concept is worth pursuing as the horse industry (especially horse racing), is a large market segment worth over US$112 billion in the USA alone. It is not uncommon in the racing industry to pay over one million dollars for a yearling with racing lineage but yet to be proven racing talent. No reasonable expense is spared to develop the horse's racing potential and cost is secondary in reaching this goal. Overtraining of horses is an ever- present concern with owners and trainers.*[1]

- **Probendo Project Human Trial – Melbourne**

Clinical Research and Ethics Committee approval has been received for the VRI BioMedical Probendo Project. The trial will be conducted at the Royal Melbourne Hospital.

This Probendo Project human trial is designed to assess whether treatment with bio-therapeutic tablets taken orally before open-heart surgery can reduce the incidence and magnitude of endotoxin rise and thus reduce the incidence of the syndrome of generalised inflammation after

[1] David Randerson BE,Msc,PhD,FAICD.

# Directors' Report

## Clinical Trials (continued)

open-heart surgery. If successful, pre-operative treatment of the Probendo Project bio-therapeutic tablet could benefit patients by improving their immune system and reducing the rate of complications in post heart surgery.

It is possible that the endotoxin molecule is involved in this syndrome by stimulating generalised inflammation after open-heart surgery. Endotoxin is found in the cell wall of some bacteria and is detectable in the blood of some patients undergoing open-heart surgery.

Work on the preparations needed to arrange and manage this human trial are well advanced. Initially 40 people will participate in this trial.

Tablet formulation is an important part of the current clinical trial programme. Considerable experimentation has been conducted in this regard to determine the most appropriate mode of bio-therapeutic delivery. This process is on-going.

The Company has been approached by several overseas organizations to conduct fully funded clinical trials in their regions. These offers are under active consideration by management.

Further ethics committee applications for human trials are being prepared for trials planned in the 2001/02 financial year.

## Commercialisation Activities

The Company's IPO prospectus stated that VRI BioMedical's immediate objectives are:

- to expedite the development and commercialisation of its existing range of projects. This is to be achieved through the management, conduct and, where appropriate, outsourcing, of further research, development and trials to bring the technology to a stage suitable to license to, or jointly commercialise with, major pharmaceutical manufacturers; and
- then to seek to enter agreements with major pharmaceutical manufacturers and distribution companies to secure future income streams for the Company from the manufacture and distribution of its products.

In the longer term, VRI BioMedical aims to identify and own a portfolio of projects which are generally less than 3 years from being suitable to license to, or jointly commercialise with, major pharmaceutical manufacturers and distributors. Projects will either be developed from internal discoveries or from technology acquired by the Company. Initially the projects will have a focus on mucosal dysfunction, an area where the Company has significant scientific and management expertise.

# Directors' Report

## Commercialisation Activities (continued)

Additionally it was stated that VRI BioMedical intends to license or otherwise outsource the manufacture, marketing and distribution of its projects to institutions or corporations with the resources for these high expenditure commercialisation processes. This will allow VRI BioMedical to maximise the application of its funds for further development of new projects while deriving revenue streams at an early stage of a particular project's development.

Capital was raised at the IPO in order to assist the Directors and management meet these objectives.

Commercialisation initiatives started in early 2001 with visits to the Northern Hemisphere where the majority of VRI's prospective customers have their head offices.

These visits have resulted in a satisfactory level of "demand pull" interest in most of the VRI projects which resulted in commercial negotiations to commence with several organizations.

At the date of this report, VRI's first commercialisation agreement had been signed with DSM NV. Commercial negotiations covering collaborative product development and licensing are continuing with several other Pharmaceutical organizations covering most of VRI's projects.

### DSM NV – collaborative research and development and commercialisation agreement.

A collaborative research and development and commercialisation agreement was signed with DSM NV. DSM is a predominant global life sciences company based in The Netherlands.

The commercial partnership combines the strength of DSM in the areas of fermentation and probiotic (healthy natural bacteria) cultures with the innovative strengths of VRI to prove the health benefits of bio-therapeutics. The joint venture will enable the development of new bio-therapeutic products with a sound scientific background on their health benefits for pharmaceutical, food and veterinary applications.

The co-development and commercial development agreement allows joint intellectual property to be cultivated and owned with both parties commercially exploiting global market opportunities and earning royalties from one another's commercial activities.

This agreement has two important parts:

- Co-development
- Commercialisation

## Commercialisation Activities (continued)

The agreement demonstrates the following benefits to VRI:

- Serious long term partnering with a multi-national. DSM is one of the world's biggest suppliers to the pharmaceuticals industry. Many of the top selling medicines in the world are based on raw materials and biological ingredients supplied by DSM. Examples are antibiotics, cardiovascular drugs, anti-depressants and drugs for the treatment of AIDS.

  The DSM group has annual sales of $14 billion and employs about 22,000 people at more than 200 sites worldwide.

- Validation of the probiotic science platform of VRI.
  - DSM is a predominant player in health sciences and has selected VRI as a partner to develop its targeted growth business globally.
  - First time the stock market would have "independent" validation of the VRI probiotic science platform.

- Gives VRI significant technology leverage through access to enabling technologies and global DSM infrastructure.
  - This will enable VRI to fast – track development of its other science projects and clinical trial programme as well as the international commercialisation programme.
  - The VRI negotiations currently underway with major pharmaceutical organizations will be favourably enhanced by the collaboration with DSM.
  - VRI will have access to the formulation, manufacturing and fermentation expertise of DSM.

- DSM contributes to VRI's project costs – cash and in-kind through technology transfer and global infrastructure support. Reduction in VRI cost of production with the provision of existing probiotic material supplied by DSM. (Details are commercially in confidence).

- The commercialisation agreement provides for the exploitation of the two distinct business fields
  - VRI Field – Pharmaceuticals, OTC, veterinary.
  - DSM Field – Food, beverages, supplements, animal feed.

- Future royalties stream to VRI based on DSM's global revenue from sales into food, feed and supplement markets. (Details are commercially in confidence)
- Lodgement of patented Intellectual Property in new probiotic strains that will yield global competitive market edge.

# Directors' Report

## VRI BioMedical's People

A fundamental strength of VRI BioMedical is its people led by strong management.

Prior to the IPO, VRI BioMedical had attracted an experienced board of directors and senior management with extensive technical and commercial experience. Its R&D team comprises leading scientists in the area of mucosal dysfunction.

During 2001 the quest to recruit talented people to support the Company's objectives continued. The recruitment of additional experienced staff took place to compliment the matrix of skills needed to migrate the Company from its research base to product development focus as a prerequisite for the commercialisation programme to be successful.

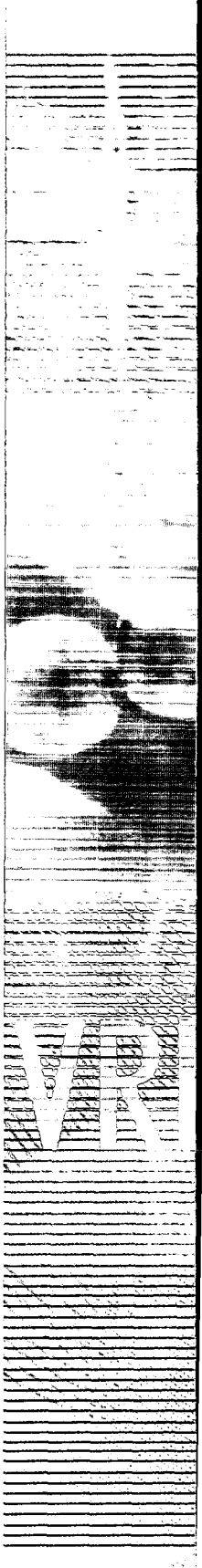
The following senior appointments are of particular note:

- **Dr Phillip Comans** has been appointed Chief Operating Officer and will head the Company's research and development function. Dr Comans' strengths lie in product development and planning. He has worked for major pharmaceutical companies including Ciba-Geigy in Switzerland and Novartis Pharmaceuticals where he held the positions of planning and project manager and international medical adviser. Dr Comans holds a PhD in Neuroscience and an MBA. He will be based in Sydney.

  Dr Comans will be responsible for all activities performed under VRI's research and development function. This includes management of the research staff, the laboratories, the biotherapeutics, diagnostics and vaccine projects, innovation activities and the clinical trials units.

- **Dr Margaret Dunkley** is employed as a Project Manager and is responsible for the management of many of the company's projects being conducted in Newcastle. Besides holding science degrees and a PhD, she has a Graduate Certificate of Management (Technology Management), is nearing completion of a Graduate Diploma in Management (Technology Management) and has a certificate in Occupational Health and Safety Management from the National Safety Council of Australia.

  She has many years experience in scientific research having published 63 scientific papers and presented 50 papers at National and International Scientific Conferences. She has worked in several research Institutions that include the Dept. of Medicine, Royal Melbourne Hospital; Walter and Eliza Hall Institute Melbourne; Australian National University, Canberra; University College, London; and University of Newcastle, Australia.



# Directors' Report

## VRI BioMedical's People (continued)

- **Ms Jane Swindells** has been appointed as the Financial Controller. Ms Swindells is a qualified Chartered Accountant with considerable commercial experience in management and financial accounting. She is responsible for the accounting and financial controls of the Company.

- **Ms Kathryn Webster** has been appointed Clinical Trials Manager. Ms Webster has experience in project management and medical research for Janssen-Cilag (a Division of Johnson and Johnson) in its immunology, cancer and psychiatry portfolios.

  Ms Webster will be a hands-on manager responsible for the clinical trials unit and all regulatory requirements. She is based in New South Wales and will operate from VRI's Newcastle research centre.

- **Mr. Henk Roubos** is engaged in a capacity to develop tablet formulation for the Company's bio-therapeutic products. Mr Roubos was for many years the Product Development Manager for Wellcome Australia Ltd. He holds a B. App. Sc (Chemistry) degree.

On the 10th September 2001, UK-based **Professor Glyn Tonge** was appointed to the Board as a non-executive Director to replace Mr Anthony Barton who is standing aside having successfully assisted the Company through its IPO. Mr Barton remains as one of VRI's largest shareholders.

Professor Tonge who holds a PhD in Microbial Physiology/Biochemistry, is a visiting Professor of Biotechnology at the University of Bath and serves on a number of government committees advising on research in the biological sciences and brings to VRI a wealth of experience in the biotechnology and biotherapy industry.

Professor Tonge has held directorships with Baring Brothers & Co. Ltd, Baring Brothers International Ltd and ING Barings. Earlier in his career he held a senior executive position with ICI (now Astra Zeneca). His time with PA Consulting Group saw him develop its biotechnology business.

He holds directorships with a large number of UK companies including Dabur Oncology Plc, Laxdale Ltd, eCare International Ltd, Site Intelligence Ltd, Penn Pharmaceuticals Ltd, Fraser Williams Plc and the Southampton Institute.

Professor Tonge is currently a non-executive director of Dabur Oncology Plc, a UK pharmaceutical company specialising in Oncology with research and development in both the UK and India.

Professor Tonge's appointment to the VRI Board will help build strategic capital market and commercial relationships in the Northern Hemisphere where VRI's main customer base is located.

# Directors' Report

## VRI BioMedical's People (continued)

The Directors would like to thank the Company's management and staff for their committed efforts to the growth of the Company that has established the solid foundations for long-term shareholder wealth creation.

## Results

The loss of the consolidated entity for the financial year after providing for income tax amounts to $3,109,026. This reflects the Company's accounting policy to expense Research and Development costs during the year as they arise.

## Significant Changes in the State of Affairs

Shareholders' equity increased from $539,795 to $9,024,579 during the year. The increase was largely a result of $12,000,000 capital raised through an Initial Public Offering and $691,625 seed capital raising. These funds have been utilised in the principal activities of the consolidated entity being the research and development of products for the prediction and prevention of disease and health conditions essentially in the field of mucosal immunology.

## Significant Events After the Balance Date

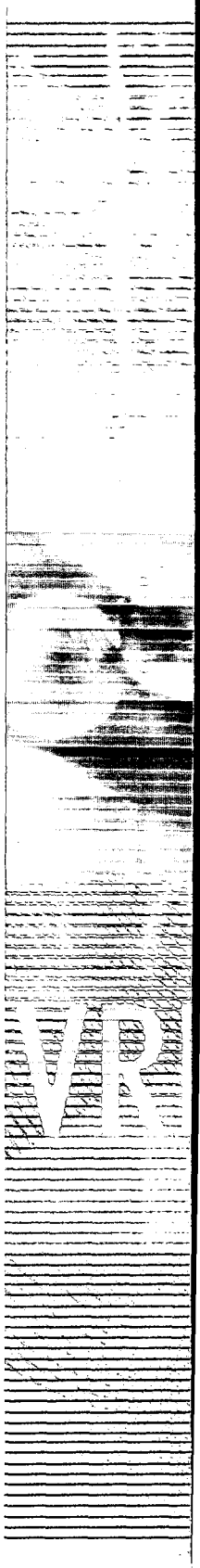
Other than the events noted below, there are no significant events after the balance date:

- A Collaborative Research and Development and Commercialisation agreement was signed with DSM NV in August 2001. This agreement is subject to the finalisation of a suitable project plan within a 60-day period. The development of this project plan is well under way at the time of this report.
- The appointment on the 10th September 2001 of Professor Glyn Tonge as a non-executive director to replace Mr Anthony Barton who resigned from the Board.
- The appointment of Dr Phillip Comans on the 17th September 2001 as Chief Operating Officer.

## Likely Developments and Expected Results

The following are likely key developments over the foreseeable future:

- Further development of the Company's Intellectual Property and patent portfolio through continuing innovative scientific research.
- Continuing commercial negotiations with potential customers (Pharmaceutical Organisations) with a view to concluding additional collaborative product development and commercialisation / licensing agreements.
- Application to Ethics Committees for additional scientific research studies some being in humans leading to clinical trials to validate the Company's technology products.



# Directors' Report

## Environmental Regulation and Performance

There have been no known breaches of any environmental regulation and performance criteria during the year.

## Unissued Shares

As at the date of this report, there were no unissued ordinary shares.

## Shares Issued as a Result of the Exercise of Options

At balance date the company has issued 1,820,000 unlisted options to employees at an exercise price of $0.50 in terms of the ESOP (Employee Share Option Plan). None of these options have been exercised.

On 8 March 2001 the company offered a Bonus Issue of Options to shareholders at the rate of 2 free options for every 5 shares held. 23,377,768 options were issued and 7,770,657 were listed on the Australian Stock Exchange. These options over ordinary shares are exerciseable at any time until 6 March 2006 at $0.75 per share. No Options have been exercised at the date of this report.

## Indemnification and Insurance of Directors and Officers

During or since the financial year, the company has paid premiums in respect of a contract insuring all the directors and officers of VRI BioMedical.

The total amount of insurance contract premiums paid was $20,233.

The Company has entered into officer protection deeds (Deeds) with each Director, the company secretary and certain members of senior management (Officers).

Under the Deeds, the Company will to the maximum extent permitted by law and the Company's constitution, indemnify the Officers against:

- Costs and expenses incurred in defending proceedings; and
- Other liabilities that may arise from their position.

Also pursuant to the Deeds, VRI BioMedical must insure the Officers against liability and provide access to all documents relevant to defending any claim brought against the Officers in their capacity as officers of the Company. The Company's subsidiaries have entered into similar documents with their respective Officers providing the same protections as the Deeds.

# Directors' Report

## Directors' and Other Officers' Emoluments

### Remuneration policy

The Remuneration Committee of the Board of Directors is responsible for determining and reviewing compensation arrangements for the directors, the chief executive officer and the executive team. The Remuneration Committee assesses the appropriateness of the nature and amount of emoluments of such officers on a periodic basis by reference to relevant employment market conditions with the overall objective of ensuring maximum stakeholder benefit from the retention of a high quality Board and executive team.

To assist in achieving these objectives, the Remuneration Committee links the nature and amount of executive directors' and officers emoluments to the company's financial and operation performance.

Details of the nature and amount of each element of the emolument of each director of the company and each of the five executive officers of the company and the consolidated entity receiving the highest emolument for the financial year are as follows:

### Emoluments* of directors of VRI BioMedical Limited

| | Annual Emoluments | | |
|---|---|---|---|
| | Base Fee/ Salary $ | Other $ | Superannuation $ |
| L Ivory | 162,036 | 1,183 | 12,962 |
| RL Clancy | 109,988 | 87,513 | – |
| KR Slatyer | 36,989 | – | 2,959 |
| KP Baxter | 16,204 | – | 1,296 |
| AP Barton | 16,204 | – | 1,296 |
| JF Cade | 16,204 | – | 1,296 |

### Emoluments of the five most highly paid executive officers# of the company and the consolidated entity

| | Annual Emoluments | | Long Term Emoluments | | |
|---|---|---|---|---|---|
| | Base Fee/ Salary $ | Bonus $ | Options @ Number | Granted $ | Superannuation |
| GTH Pang | 39,000 | 60,000 | 840,000 | 69,720 | 57,750 |
| JR Frame | 92,592 | 36,417 | 840,000 | 69,720 | 20,987 |
| G Bezer | 86,004 | – | – | – | 33,900 |
| PL Conway | 39,351 | – | 140,000 | 11,620 | 3,148 |
| M Dunkley** | 25,513 | – | – | – | 7,659 |

The terms 'director' and 'officer' have been treated as mutually exclusive for the purposes of this disclosure.

* The elements of emoluments have been determined on the basis of the cost to the company and the consolidated entity.

\# Executives are those directly accountable and responsible for the operational management and strategic direction of the company and the consolidated entity.

@ These employee share Options granted under the Employee Share Option Plan are exercisable at $0.50 per Ordinary share. They have been valued at 8.3c per option. The value of these options has not been included in the Remuneration of Executives as disclosed in Note 21.

** Dr M Dunkley commenced employment with the Company on 12 February 2001.

The above amounts do not include expenses incurred by Directors and their related entities and executive officers that were reimbursed by the Company.

# Directors' Report

## Directors' Meetings

The numbers of meetings of directors (including meetings of committees of directors) held during the year and the number of meetings attended by each director were as follows:

| | Directors' Meetings | Meetings of Committees: Audit and Risk Management | Meetings of Committees: Remuneration |
|---|---|---|---|
| **Number of meetings held:** | 12 | 6 | 2 |
| **Number of meetings attended:** | | | |
| L Ivory | 12 | | |
| KR Slatyer | 12 | 6 | 2 |
| RL Clancy | 11 | | |
| KP Baxter* | 8 | 6 | 2 |
| AP Barton | 10 | | |
| JF Cade* | 7 | 6 | 2 |

**Notes:**

* Appointed as a Director on 1 November 2000.

### Committee membership

As at the date of this report, the Company had an Audit and Risk Management Committee and a Remuneration Committee, of the Board of Directors.

Members acting on the Board committees during the year were:

| Audit and Risk Management | Remuneration |
|---|---|
| JF Cade (Chairman) | KP Baxter (Chairman) |
| KP Baxter | JF Cade |
| KR Slatyer | KR Slatyer |

# Directors' Report

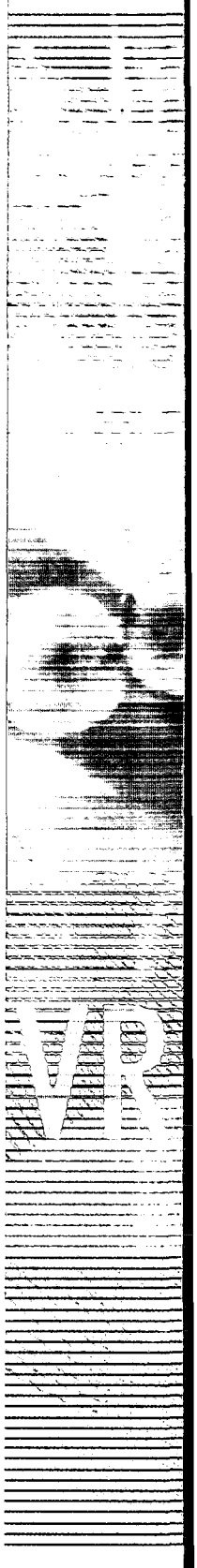
## Corporate Governance

In recognising the need for the highest standards of corporate behaviour and accountability, the directors of VRI BioMedical Limited support and have adhered to the principles of corporate governance. The company's corporate governance statement is contained after the ASX additional information section of this annual report.

Signed in accordance with a resolution of the directors.

L Ivory
*Chairman*

Perth, 25 September 2001



# Statement of Financial Performance

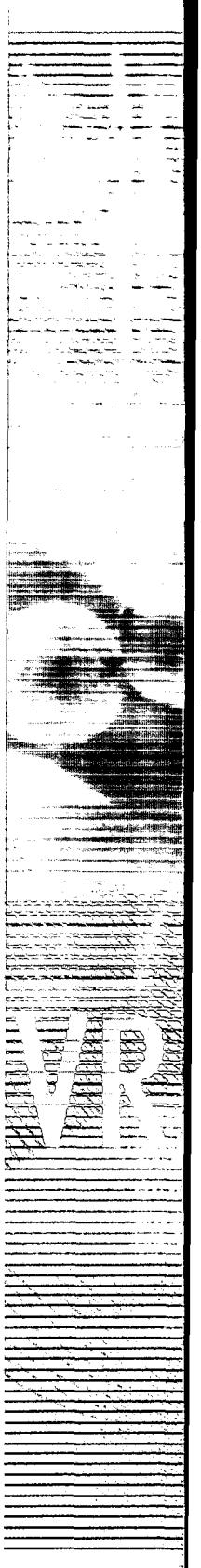
for the Year Ended 30 June 2001

| | NOTES | CONSOLIDATED | | VRI BIOMEDICAL LIMITED | |
|---|---|---|---|---|---|
| | | 2001 $ | 2000 $ | 2001 $ | 2000 $ |
| REVENUES FROM ORDINARY ACTIVITIES | 2 | 329,390 | 9,423 | – | 9,423 |
| Depreciation and amortisation expenses | 3 | (11,646) | (1,088) | – | – |
| Salaries and employee benefits expense | | (533,894) | – | – | – |
| Research and development expenditure | 3 | (1,568,101) | (201,944) | – | – |
| Other expenses from ordinary activities | 3 | (1,324,775) | (1,232,650) | (3,108,926) | (1,435,472) |
| LOSS FROM ORDINARY ACTIVITIES BEFORE INCOME TAX EXPENSE | | (3,109,026) | (1,426,259) | (3,108,926) | (1,426,049) |
| INCOME TAX EXPENSE RELATING TO ORDINARY ACTIVITIES | 4 | – | – | – | – |
| OPERATING LOSS AFTER INCOME TAX EXPENSES | 14 | (3,109,026) | (1,426,259) | (3,108,926) | (1,426,049) |
| Basic earnings/(loss) per share (cents per share) | 19 | (6.10) | (7.22) | | |

# Statement of Financial Position

as at 30 June 2001

| | NOTES | CONSOLIDATED | | VRI BIOMEDICAL LIMITED | |
|---|---|---|---|---|---|
| | | 2001 $ | 2000 $ | 2001 $ | 2000 $ |
| **CURRENT ASSETS** | | | | | |
| Cash assets | | 259,250 | 518,620 | 259,250 | 518,620 |
| Receivables | 5 | 9,104,450 | 3,579 | 9,104,450 | 3,579 |
| Other | 7 | 5,876 | 87,824 | 5,876 | 87,824 |
| **TOTAL CURRENT ASSETS** | | 9,369,576 | 610,023 | 9,369,576 | 610,023 |
| **NON-CURRENT ASSETS** | | | | | |
| Receivables | 6 | – | – | – | – |
| Investments | 8 | – | – | 310 | 210 |
| Property, Plant & Equipment | 9 | 191,679 | 38,886 | 191,679 | 38,886 |
| Intangibles | 10 | 2,400 | 2,400 | 2,400 | 2,400 |
| **TOTAL NON-CURRENT ASSETS** | | 194,079 | 41,286 | 194,389 | 41,496 |
| **TOTAL ASSETS** | | 9,563,655 | 651,309 | 9,563,965 | 651,519 |
| **CURRENT LIABILITIES** | | | | | |
| Payables | 11 | 502,734 | 111,514 | 502,734 | 111,514 |
| Provisions | 12 | 36,342 | – | 36,342 | – |
| **TOTAL CURRENT LIABILITIES** | | 539,076 | 111,514 | 539,076 | 111,514 |
| **TOTAL LIABILITIES** | | 539,076 | 111,514 | 539,076 | 111,514 |
| **NET ASSETS** | | 9,024,579 | 539,795 | 9,024,889 | 540,005 |
| **EQUITY** | | | | | |
| Parent Entity Interest | | | | | |
| Contributed Equity | 13 | 13,560,013 | 1,966,203 | 13,560,013 | 1,966,203 |
| Accumulated Losses | 14 | (4,535,434) | (1,426,408) | (4,535,124) | (1,426,198) |
| **TOTAL EQUITY** | | 9,024,579 | 539,795 | 9,024,889 | 540,005 |



# Statement of Cash Flows

for the Year Ended 30 June 2001

| | NOTES | CONSOLIDATED | | VRI BIOMEDICAL LIMITED | |
|---|---|---|---|---|---|
| | | 2001 | 2000 | 2001 | 2000 |
| | | $ | $ | $ | $ |
| **CASH FLOWS FROM OPERATING ACTIVITIES** | | | | | |
| Payments to Suppliers and Employees | | (3,313,399) | (1,130,789) | 122,267 | 301,877 |
| Interest Received | | 277,033 | 9,423 | – | 9,423 |
| Goods and Services Tax | | 116,487 | – | – | – |
| **NET CASH FLOWS FROM (USED IN) OPERATING ACTIVITIES** | 15 | (2,919,879) | (1,121,366) | 122,267 | 311,300 |
| **CASH FLOWS FROM INVESTING ACTIVITIES** | | | | | |
| Acquisition of Property, Plant & Equipment | | (159,954) | (39,974) | (159,954) | (39,974) |
| Purchase of Shares in Subsidiaries | | – | – | (100) | (210) |
| Advances to Subsidiaries/Related Parties | | – | – | (3,042,046) | (1,432,456) |
| Other – Purchase of Bank Bills | | (8,861,171) | – | (8,861,171) | – |
| **NET CASH FLOWS FROM/ (USED IN) INVESTING ACTIVITIES** | | (9,021,125) | (39,974) | (12,063,271) | (1,472,640) |
| **CASH FLOWS FROM FINANCING ACTIVITIES** | | | | | |
| Proceeds from Issue of Ordinary Shares | | 12,604,625 | 1,839,251 | 12,604,625 | 1,839,251 |
| Payment of Share Issue Costs | | (922,991) | (87,824) | ( 922,991) | (87,824) |
| Repayment of Borrowings – Other | | – | (71,470) | – | (71,470) |
| **NET CASH FLOWS FROM/(USED IN) FINANCING ACTIVITIES** | | 11,681,634 | 1,679,957 | 11,681,634 | 1,679,957 |
| **NET INCREASE/(DECREASE) IN CASH HELD** | | (259,370) | 518,617 | (259,370) | 518,617 |
| Add Opening Cash brought forward | | 518,620 | 3 | 518,620 | 3 |
| **CLOSING CASH CARRIED FORWARD** | | 259,250 | 518,620 | 259,250 | 518,620 |

# Notes to and Forming Part of the Financial Statements

**for the Year Ended 30 June 2001**

## 1. Summary of Significant Accounting Policies

### (a) Basis of Accounting

The financial report is a general purpose financial report that has been prepared in accordance with the requirements of the *Corporations Act 2001* which includes applicable Accounting Standards. Other mandatory professional reporting requirements (Urgent Issues Group Consensus Views) have also been complied with.

The financial statements have been prepared in accordance with the historical cost convention, except as otherwise stated.

### (b) Changes in Accounting Policies

The accounting policies adopted are consistent with those of the previous year.

### (c) Principles of Consolidation

The consolidated financial statements are those of the consolidated entity, comprising VRI BioMedical Limited (the parent entity) and all entities which VRI BioMedical Limited controlled from time to time during the year and at the balance date.

Information from the financial statements of subsidiaries is included from the date the parent company obtains control until such time control ceases. Where there is loss of control of a subsidiary, the consolidated financial statements include the results for the part of the reporting period during which the parent company has control.

The financial statements of subsidiaries are prepared for the same reporting period as the parent entity, using consistent accounting policies. Adjustments are made to bring into line any dissimilar accounting policies which may exist.

All intercompany balances and transactions, including unrealised profits arising from intra-group transactions, have been eliminated in full. Unrealised losses are eliminated unless costs cannot be recovered.

### (d) Cash and cash equivalents

Cash on hand and in banks and short term deposits are stated at the lower of cost and net realisable value.

Cash includes cash on hand and in banks, and money market investments readily convertible to cash within 2 working days, net of outstanding bank overdrafts.

Bank overdrafts are carried at the principal amount. Interest is charged as an expense as it accrues.

# Notes to and Forming Part of the Financial Statements

for the Year Ended 30 June 2001

## 1. Summary of Significant Accounting Policies (continued)

### (e) Trade and other receivables

Trade receivables are recognised and carried at original invoice amount less a provision for any uncollectable debts. An estimate for doubtful debts is made when collection of the full amount is no longer probable. Bad debts are written off as incurred.

Receivables from related parties are recognised and carried at the nominal amount due. Interest is taken up as income on an accrual basis.

### (f) Investments

Investments in subsidiaries are carried at cost.

### (g) Recoverable Amount

Non-current assets are not carried at an amount above their recoverable amount, and where carrying values exceed this recoverable amount assets are written down. In determining recoverable amount, the expected cash flows have not been discounted to their present value using a market determined risk adjustment discount rate.

### (h) Property, plant and equipment

Items of plant and equipment are recorded in the financial report at cost. Depreciation is calculated based on the determined useful life of the plant and equipment ranging from 4 to 20 years.

### (i) Intangibles

Logo expenses as incurred by the company have been capitalised as an intangible asset in the financial report. This amount is amortised over the useful life of the asset.

### (j) Research and development

Research and development costs are expensed as incurred, except where future benefits are expected, beyond any reasonable doubt, to exceed those costs.

### (k) Trade and other payables

Liabilities for trade creditors and other amounts are carried at cost which is the fair value of the consideration to be paid in the future for goods and services received, whether or not billed to the consolidated entity.

Payables to related parties are carried at the principal amount. Interest, where charged by the lender, is recognised as an expense on an accrual basis.

# Notes to and Forming Part of the Financial Statements

for the Year Ended 30 June 2001

## 1. Summary of Significant Accounting Policies (continued)

### (l) Share capital

Ordinary share capital is recognised at the fair value of the consideration received by the company.

Any transaction costs arising on ordinary shares issued at balance date are recognised directly in equity as a reduction of the share proceeds received.

### (m) Revenue recognition

Revenue is recognised to the extent that it is probable that the economic benefits will flow to the entity and the revenue can be reliably measured. The following specific recognition criteria must also be met before revenue is recognised:

*Interest*

Control of a right to receive consideration for the provision of, or investment in, assets has been attained.

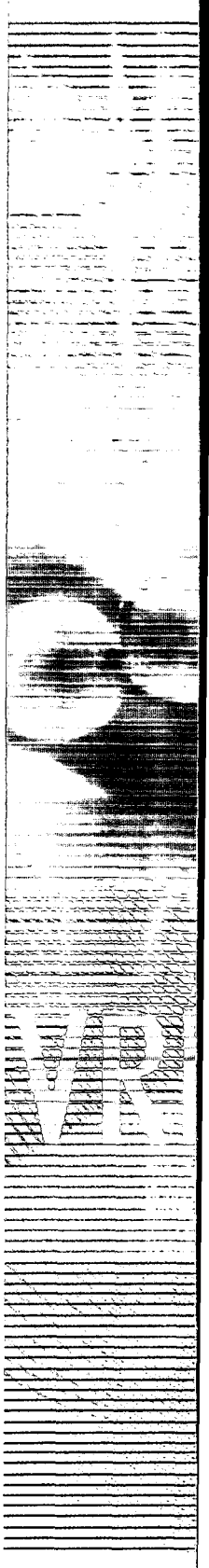
### (n) Income tax

Tax-effect accounting is applied using the liability method whereby income tax is regarded as an expense and is calculated on the accounting profit after allowing for permanent differences. To the extent timing differences occur between the time items are recognised in the financial statements and when items are taken into account in determining taxable income, the net related taxation benefit or liability, calculated at current rates, is disclosed as a future income tax benefit or a provision for deferred income tax. The net future income tax benefit relating to tax losses and timing differences is not carried forward as an asset unless the benefit is virtually certain of being realised.

### (o) Employee entitlements

Provision is made for employee entitlement benefits accumulated as a result of employees rendering services up to the reporting date. These benefits include wages and salaries, annual leave, sick leave and long service leave.

Liabilities arising in respect of wages and salaries, annual leave, sick leave and any other employee entitlements expected to be settled within twelve months of the reporting date are measured at their nominal amounts. All other employee entitlement liabilities are measured at the present value of the estimated future cash outflow to be made in respect of services provided by employees up to the reporting date. In determining the present value of future cash outflows, the interest rates attaching to government guaranteed securities which have terms to maturity approximating the terms of the related liability are used.



# Notes to and Forming Part of the Financial Statements

for the Year Ended 30 June 2001

## 1. Summary of Significant Accounting Policies (continued)

### (o) Employee entitlements (continued)

Employee entitlements expenses and revenues arising in respect of the following categories:

- Wages and salaries, non-monetary benefits, annual leave, long service leave, sick leave and other leave entitlements; and
- Other types of employee entitlements

Are charged against profits on a net basis in their respective categories.

### (p) Earnings per share

Basic earnings per share is determined by dividing the profit from ordinary activities after related income tax expense by the weighted average number of ordinary shares outstanding during the financial year.

Diluted earnings per share is determined by dividing the profit from ordinary activities after related income tax expense adjusted for the effect of earnings on potential ordinary shares, by the weighted average number of ordinary shares (both issued and potentially dilutive) outstanding during the financial year. The options exercise price is greater than the current market price of the ordinary shares. Therefore, these options are unlikely to be exercised and diluted earnings per share are not materially different to basic earnings per share.

As there were no unissued ordinary shares, diluted earnings per share are not materially different to basic earnings per share.

| | CONSOLIDATED | | VRI BIOMEDICAL LIMITED | |
|---|---|---|---|---|
| | 2001 | 2000 | 2001 | 2000 |
| | $ | $ | $ | $ |
| **2. Revenue from Ordinary Activities** | | | | |
| Included in the operating loss is the following revenue arising from operating activities: | | | | |
| Interest received | | | | |
| – Other persons/corporations | 329,390 | 9,423 | – | 9,423 |
| **3. Expenses and Losses** | | | | |
| **Expenses** | | | | |
| – Depreciation of non-current assets | 11,646 | 1,088 | – | – |
| – Research and Development costs | 1,568,101 | 201,944 | – | – |
| – Provision for Non Recovery of Loans | – | – | 3,042,146 | 1,432,456 |
| – Rental Costs | 97,283 | 66,888 | – | – |
| – Consultancy fees | 248,693 | 956,833 | – | – |

# Notes to and Forming Part of the Financial Statements

**for the Year Ended 30 June 2001**

## 4. Income Tax Expense

| | CONSOLIDATED | | VRI BIOMEDICAL LIMITED | |
|---|---|---|---|---|
| | 2001 | 2000 | 2001 | 2000 |
| | $ | $ | $ | $ |
| The prima facie tax expense (benefit) on the operating profit/(loss) from ordinary activities is reconciled to the income tax provided in the financial statements as follows: | | | | |
| Prima facie tax expense/(benefit) on operating loss from ordinary activities at 34% (2000: 36%) | (1,057,069) | (513,453) | (1,057,069) | (513,377) |
| Tax Effect of Permanent Differences | | | | |
| Amortisation – formation expenses | 1,679 | 6,142 | - | - |
| Entertainment | 3,068 | 2,951 | - | - |
| Prospectus costs | 22,739 | - | 22,739 | - |
| Provision for Non Recovery of Loans | - | - | 1,034,330 | 515,684 |
| Research & Development accelerated claim | (82,669) | (85,110) | - | (191) |
| Taxable Loss transferred from controlled entity | - | 2,116 | - | (2,116) |
| Future Income Tax Benefit not brought to account | 1,112,252 | 587,354 | - | - |
| Income tax expense/(benefit) attributable to loss from ordinary activities | - | - | - | - |

As at 30 June 2001 the consolidated entity has not brought to account a future tax benefit (at 30%) of $1,459,569 (2000: $1,637,420) as realisation of the benefit is not virtually certain.

The future income tax benefit will only be obtained if:

(a) future assessable income is derived of a nature and of an amount sufficient to enable the benefit to be realised,

(b) the condition for deductibility imposed by tax legislation continue to be complied with, and

(c) no changes in tax legislation adversely affect the consolidated entity in realising the benefit.

# Notes to and Forming Part of the Financial Statements

for the Year Ended 30 June 2001

| | CONSOLIDATED | | VRI BIOMEDICAL LIMITED | |
|---|---|---|---|---|
| | 2001 | 2000 | 2001 | 2000 |
| | $ | $ | $ | $ |
| **5. Receivables** | | | | |
| **Current** | | | | |
| Bank Bills | 8,950,000 | – | 8,950,000 | – |
| GST – Input Tax Credits | 152,978 | 422 | 152,978 | 422 |
| Short-term deposits | 1,472 | – | 1,472 | – |
| Other Debtors | – | 3,157 | – | 3,157 |
| | $9,104,450 | $3,579 | $9,104,450 | $3,579 |
| **6. Receivables** (continued) | | | | |
| **Non-Current** | | | | |
| Loans to Subsidiaries | | | | |
| – Equine Alert Pty Ltd | – | – | 254,936 | 27,213 |
| – Herbatex Pty Ltd | – | – | 27,213 | 27,213 |
| – Novoceutics Pty Ltd | – | – | 135,641 | 27,213 |
| – Auticoll Pty Ltd | – | – | 153,109 | 28,563 |
| – Vasse Research Institute Pty Ltd | – | – | 985 | 985 |
| – SIDS Alert Pty Ltd | – | – | 429,403 | 195,017 |
| – VRI Therapeutics & Vaccines Pty Ltd | – | – | 1,845 | 1,845 |
| – Performax Alert Pty Ltd | – | – | 437,975 | 188,359 |
| – Candivax Pty Ltd | – | – | 263,030 | 84,214 |
| – VRI Diagnostics Pty Ltd | – | – | 1,345 | 1,345 |
| – ONCO Alert Pty Ltd | – | – | 296,200 | 172,583 |
| – Pneumobiotics Pty Ltd | – | – | 327,812 | 163,699 |
| – VRI Biotherapeutics Pty Ltd | – | – | 198,027 | 80,022 |
| – Probendo Pty Ltd | – | – | 183,320 | 79,947 |
| – Helirad Alert Pty Ltd | – | – | 179,572 | 27,213 |
| – Mucoprotec Pty Ltd | – | – | 492,996 | 83,859 |
| – Probiall Pty Ltd | – | – | 416,591 | 163,219 |
| – CP Alert Pty Ltd | – | – | 79,947 | 79,947 |
| – Secril 4 Alert Pty Ltd | – | – | 121,765 | – |
| – Atheromastat Pty Ltd | – | – | 114,877 | – |
| – Probiadd Pty Ltd | – | – | 142,433 | – |
| – Sphere Animal Health Pty Ltd | – | – | 215,580 | – |
| | – | – | 4,474,602 | 1,432,456 |
| Less: Provision for Non Recovery of Loans | – | – | (4,474,602) | (1,432,456) |
| | $– | $– | $– | $– |

These loans are unsecured and are not subject to an interest charge.

# Notes to and Forming Part of the Financial Statements

**for the Year Ended 30 June 2001**

| | CONSOLIDATED | | VRI BIOMEDICAL LIMITED | |
|---|---|---|---|---|
| | 2001 | 2000 | 2001 | 2000 |
| | $ | $ | $ | $ |
| **7. Other Current Assets** | | | | |
| Prepayments | $5,876 | $87,824 | $5,876 | $87,824 |
| **8. Investments** | | | | |
| Non-Current | | | | |
| Shares in Subsidiaries | | | | |
| – Sphere Animal Health Pty Ltd | – | – | 100 | – |
| – VRI Diagnostics Pty Ltd | – | – | 100 | 100 |
| – VRI Therapeutics & Vaccines Pty Ltd | – | – | 100 | 100 |
| – Vasse Research Institute Pty Ltd | – | – | 10 | 10 |
| | $– | $– | $310 | $210 |
| (Refer to Note 24) | | | | |
| **9. Property, Plant & Equipment** | | | | |
| Plant and Equipment – at cost | 53,490 | 38,500 | 53,490 | 38,500 |
| Provision for depreciation | (7,785) | (989) | (7,785) | (989) |
| | 45,705 | 37,511 | 45,705 | 37,511 |
| Office Equipment – at cost | 150,923 | 1,474 | 150,923 | 1,474 |
| Provision for depreciation | (4,949) | (99) | (4,949) | (99) |
| | 145,974 | 1,375 | 145,974 | 1,375 |
| TOTAL | $191,679 | $38,886 | $191,679 | $38,886 |
| **(a) Reconciliations** | | | | |
| Plant and Equipment | | | | |
| Carrying amount at beginning | 37,511 | – | 37,511 | – |
| Additions | 14,990 | 38,500 | 14,990 | 38,500 |
| Depreciation expense | (6,796) | (989) | (6,796) | (989) |
| | 45,705 | 37,511 | 45,705 | 37,511 |
| Office Equipment | | | | |
| Carrying amount at beginning | 1,375 | – | 1,375 | – |
| Additions | 149,449 | 1,474 | 149,449 | 1,474 |
| Depreciation expense | (4,850) | (99) | (4,850) | (99) |
| | 145,974 | 1,375 | 145,974 | 1,375 |

# Notes to and Forming Part of the Financial Statements

for the Year Ended 30 June 2001

| | CONSOLIDATED | | VRI BIOMEDICAL LIMITED | |
|---|---|---|---|---|
| | 2001 | 2000 | 2001 | 2000 |
| | $ | $ | $ | $ |
| **10. Intangibles** | | | | |
| Logo Expenses – at cost | $2,400 | $2,400 | $2,400 | $2,400 |
| **11. Payables** | | | | |
| **Current** | | | | |
| Trade Creditors | 466,282 | 111,514 | 466,282 | 111,514 |
| Aggregate amounts payable to related parties | | | | |
| Director – related entity | 36,452 | – | 36,452 | – |
| | $502,734 | $111,514 | $502,734 | $111,514 |
| **12. Provisions** | | | | |
| **Current** | | | | |
| Employee Entitlements | $36,342 | $– | $36,342 | $– |
| **13. Contributed Equity** | | | | |
| (a) **Issued and Paid Up Capital** | | | | |
| 58,444,333 (2000: 40,600,000) Ordinary Shares fully paid | $13,560,013 | $1,966,203 | $13,560,013 | $1,966,203 |

(b) **Movements in Shares on issue**

| | 2001 | | 2000 | |
|---|---|---|---|---|
| | Number of Shares | $ | Number of Shares | $ |
| Beginning of the financial year | 40,600,000 | 1,966,203 | 3 | 3 |
| Issued during the year | | | | |
| – seed capital investors | 1,844,333 | 691,625 | 40,599,997 | 1,966,200 |
| – initial public offering | 16,000,000 | 12,000,000 | – | – |
| Less capitalised prospectus costs | – | (1,097,815) | – | – |
| End of the financial year | 58,444,333 | $13,560,013 | 40,600,000 | $1,966,203 |

# Notes to and Forming Part of the Financial Statements

for the Year Ended 30 June 2001

## 13. Contributed Equity (continued)

### (c) Share Options

**Listed options over ordinary shares:**

On 8 March 2001 VRI BioMedical Ltd offered a Bonus Issue of Options to shareholders at the rate of 2 free options for every 5 shares held. 23,377,768 options were issued and 7,770,657 listed on the Australian Stock Exchange.

These options over ordinary shares are exercisable at any time until 6 March 2006 at $0.75 per share. No Options have been exercised until the date of this report.

**Employee Share Option Plan**

The Board has adopted an Employee Share Option Plan (ESOP) to provide a long-term incentive for employees and directors of VRI BioMedical. The ESOP enables eligible persons to participate in the Company's future growth by contributing to increasing profitability and returns to Shareholders.

A summary of the ESOP is set out below:

Full or permanent part-time employees and directors of VRI BioMedical are eligible to participate, by invitation, in the ESOP;

The Directors may from time to time, in their absolute discretion, issue such number of options on such terms as they determine to eligible participants;

These options are not listed on the Australian Stock Exchange and therefore have no market value;

Issued options shall be exercisable within such period(s) or upon such event(s) as the Directors may specify at the date of issue of the options;

Options will be issued free of charge to the participants in the ESOP. The exercise price of each option offered pursuant to the ESOP is at the discretion of the Directors;

Under this scheme the following were granted:

| | Number of Options |
|---|---|
| Issued during the year exercisable at $0.50 on or before 13 October 2005 | 1,920,000 |
| Cancelled during the year | (100,000) |
| Outstanding at 30 June 2001 exercisable at $0.50 on or before 13 October 2005 | 1,820,000 |

# Notes to and Forming Part of the Financial Statements

**for the Year Ended 30 June 2001**

## 13. Contributed Equity (continued)

**(d) Terms and condition of contribution equity**

**Ordinary Shares**

Ordinary shares have the right to receive dividends as declared and in the event of winding up the company, to participate in the proceeds from the sale of all surplus assets in proportion to the number of and amounts paid up on shares held.

Ordinary shares entitle their holder to one vote either in person or by proxy, at a meeting of the company.

| | CONSOLIDATED | | VRI BIOMEDICAL LIMITED | |
|---|---|---|---|---|
| | 2001 | 2000 | 2001 | 2000 |
| | $ | $ | $ | $ |
| **14. Accumulated Losses** | | | | |
| Accumulated losses | | | | |
| Balance at beginning of year | 1,426,408 | 149 | 1,426,198 | 149 |
| Operating loss after Income Tax | 3,109,026 | 1,426,259 | 3,108,926 | 1,426,049 |
| Balance at end of year | 4,535,434 | 1,426,408 | 4,535,124 | 1,426,198 |
| **15. Statement of Cash Flows** | | | | |
| **(a) Reconciliation of the Operating profit after tax to the Net Cash Flows from Operations** | | | | |
| Operating profit/(loss) after tax | (3,109,026) | (1,426,259) | (3,108,926) | (1,426,049) |
| Depreciation of Non Current Assets | 11,646 | 1,088 | 11,646 | 1,088 |
| Provision for non recovery of Loans | – | – | 3,042,146 | 1,432,456 |
| Consultancy fees settled by way of issue of 9,509,289 fully paid ordinary shares | – | 126,949 | – | 126,949 |
| Changes in assets and liabilities | | | | |
| Creditors | 386,606 | 111,514 | 386,506 | 111,514 |
| Other Debtors | (5,876) | (3,579) | (5,876) | (3,579) |
| Intangibles | – | 68,921 | – | 68,921 |
| Receivables | ( 203,229) | – | ( 203,229) | – |
| **Net cash flow from/(used in) operating activities** | (2,919,879) | (1,121,366) | 122,267 | 311,300 |

# Notes to and Forming Part of the Financial Statements

**for the Year Ended 30 June 2001**

| | CONSOLIDATED | | VRI BIOMEDICAL LIMITED | |
|---|---|---|---|---|
| | 2001 | 2000 | 2001 | 2000 |
| | $ | $ | $ | $ |

## 15. Statement of Cash Flows (continued)

**(b) Reconciliation of cash**

Cash balance comprises:

| | | | | |
|---|---|---|---|---|
| – Cash on hand | 259,250 | 518,620 | 259,250 | 518,620 |

All subsidiaries were acquired for a nominal value and had no assets or liabilities at the date of acquisition.

## 16. Expenditure Commitments

Lease expenditure commitments:

Operating leases

Minimum lease payments

| | | | | |
|---|---|---|---|---|
| – not later than one year | 47,800 | 21,450 | – | – |
| – later than one year and not later than five years | 99,583 | – | – | – |
| Aggregate lease expenditure contracted for at balance date | 147,383 | 21,450 | – | – |

Operating lease relates to Perth office space for a lease term expiring 1 August 2004.

## 17. Subsequent Events

There have been no subsequent events that have an effect on the financial position of the Company as at the date of this report.

# Notes to and Forming Part of the Financial Statements

for the Year Ended 30 June 2001

| | CONSOLIDATED | | VRI BIOMEDICAL LIMITED | |
|---|---|---|---|---|
| | 2001 | 2000 | 2001 | 2000 |
| | $ | $ | $ | $ |

## 18. Economic Dependency

There are no known economic dependencies effecting the operation of VRI BioMedical Limited.

## 19. Earnings per Share

| | | | | |
|---|---|---|---|---|
| Basic earnings/(loss) per share | (6.10c) | (7.22c) | – | – |
| Diluted earnings per share are not materially different to basic earnings per share | | | | |
| Weighted average number of ordinary shares on issue used in the calculation of basic earnings per share. | 50,950,118 | 19,753,004 | – | – |

## 20. Remuneration of Directors

**(a) Director's remuneration**

| | | | | |
|---|---|---|---|---|
| Income paid or payable, or otherwise made available, in respect of the financial year, to directors or their related entities, either directly or indirectly amounted to: | 466,130 | 294,156 | – | – |

The number of directors of VRI BioMedical Limited to whom payments were made either directly or indirectly whose income falls within the following bands is:

| | 2001 No | 2000 No |
|---|---|---|
| $10,000 – $19,999 | 2 | – |
| $30,000 – $39,999 | 1 | – |
| $50,000 – $59,999 | – | 1 |
| $60,000 – $69,999 | 1 | – |
| $100,000 – $109,999 | – | 1 |
| $130,000 – $139,999 | – | 1 |
| $170,000 – $179,999 | 1 | – |
| $190,000 – $199,999 | 1 | – |

In the opinion of directors, remuneration paid to directors is considered reasonable

# Notes to and Forming Part of the Financial Statements

**for the Year Ended 30 June 2001**

| | CONSOLIDATED | | VRI BIOMEDICAL LIMITED | |
|---|---|---|---|---|
| | 2001 | 2000 | 2001 | 2000 |
| | $ | $ | $ | $ |

## 21. Remuneration of Executives

| | | | | |
|---|---|---|---|---|
| Remuneration received or due and receivable by executive officers of the consolidated entity whose remuneration is $100,000 or more, from entities in the consolidated entity or a related party, in connection with the management of the affairs of the entities in the consolidated entity whether as an executive officer or otherwise. | 602,831 | - | - | - |

The number of executives of the consolidated entity and the Company whose remuneration falls within the following bands:

| | No. | No. |
|---|---|---|
| $110,000 - $119,999 | 1 | - |
| $140,000 - $149,999 | 1 | - |
| $150,000 - $159,999 | 1 | - |
| $170,000 - $179,999 | 1 | - |

## 22. Auditors' Remuneration

| | | | | |
|---|---|---|---|---|
| Amounts received or due and receivable by Ernst & Young for: | | | | |
| – an audit or review of the financial report of the entity | 5,323 | 10,000 | – | – |
| – other services in relation to the entity and any other entity in the consolidated entity | 45,205 | – | – | – |
| | 50,528 | 10,000 | – | – |

# Notes to and Forming Part of the Financial Statements

**for the Year Ended 30 June 2001**

## 23. Related Party Disclosures

(a) The directors of VRI BioMedical Limited, during the financial year were:

| | |
|---|---|
| Leon Ivory | |
| Anthony Peter Barton | *(Resigned 10th September 2001)* |
| Kenneth Peter Baxter | *(Appointed 1st November 2000)* |
| John Francis Cade | *(Appointed 1st November 2000)* |
| Robert Llewellyn Clancy | |
| Kim Robert Slatyer | |
| Glyn Michael Tonge | *(Appointed 10th September 2001)* |

(b) The following related party transactions occurred during the financial year:

*(i) Transactions with related parties in wholly owned group.*

Payments were made by VRI BioMedical Limited during the year on behalf of its subsidiaries. These payments have been reflected through the loan accounts to each of the subsidiaries as shown in note 6 of the financial statements totalling $3,042,146. These loans are unsecured and are not subject to an interest charge.

*(ii) Transactions with director-related entities*

These transactions have not been included in Directors' remuneration.

- $28,790 has been paid and payable to Trivenia Pty Ltd as trustee for The Kim Slatyer Trust of which KR Slatyer is a director, for consultancy fees
- $21,994 has been paid to Maktram Pty Ltd and/or RL Clancy for office rental. RL Clancy is a director of Maktram Pty Ltd.
- $16,650 has been paid to Baxter & Associates Pty Ltd for Sydney office rental and consultancy fees. KP Baxter is a director of Baxter & Associates Pty Ltd.
- $145,000 has been paid to the University of Newcastle in terms of the contract with the University for part of RL Clancy's time, part of his secretary's time and rental for the Newcastle laboratory facilities.
- $853,438 has been paid and payable to TUNRA Ltd for the supply of contactors, laboratory supplies, travel expenses and administration fees. RL Clancy was a director of TUNRA Ltd during the year until his resignation on 29 May, 2001.

In addition, directors have been reimbursed for expenditure incurred on behalf of VRI BioMedical Limited.

# Notes to and Forming Part of the Financial Statements

**for the Year Ended 30 June 2001**

## 23. Related Party Disclosures (continued)

(c) Equity instruments of directors

**Interests at balance date**

Interests in the equity instruments of entities in the consolidated entity held by directors of the reporting entity and their director-related entities at balance date, being the number of instruments held:

| Director | Ordinary Shares Fully Paid | | Options over Ordinary Shares | |
|---|---|---|---|---|
| | Number 2001 | Number 2000 | Number 2001 | Number 2000 |
| L Ivory | 9,000,000 | 9,000,000 | 3,600,001 | – |
| KR Slatyer | 9,000,000 | 9,000,000 | 3,600,001 | – |
| RL Clancy | 9,000,000 | 9,000,000 | 3,600,001 | – |
| KP Baxter | 11,500 | – | 20,800 | – |
| JF Cade | 268,100 | – | 107,240 | – |

Movements in directors' equity holdings:

During the year Mr K P Baxter acquired 11,500 Ordinary Shares and 20,800 Options over Ordinary Shares on an arm's length basis at market value.

Prof J F Cade acquired 267,000 Ordinary Shares as a seed capital investor in October 2000 at an average exercise price of $0.375 and 106,800 Options over Ordinary Shares in terms of the Bonus Options Issue of 2 options for every 5 ordinary shares held. He acquired 1,100 Ordinary Shares and 440 Options over Ordinary Shares on an arm's length basis at market value.

L Ivory holds his shares through Ivory & Company Pty Ltd as trustee for The Ivory Trust.
KR Slatyer holds his shares through Trivenia Pty Ltd as trustee for The Kim Slatyer Trust.
RL Clancy holds his shares through Maktram Pty Ltd.
KP Baxter holds 2,500 shares and 7,200 options through Baxter & Associates Pty Ltd

# Notes to and Forming Part of the Financial Statements

**for the Year Ended 30 June 2001**

## 24. Interests in Subsidiaries

| Name | Country of Incorporation | Percentage of equity interest held by the consolidated entity |
|---|---|---|
| Vasse Research Institute Pty Ltd | Australia | 100% |
| VRI Diagnostics Pty Ltd | Australia | 100% and its controlled entities |
| Equine Alert Pty Ltd | Australia | 100% |
| Helirad Alert Pty Ltd | Australia | 100% |
| CP Alert Pty Ltd | Australia | 100% |
| ONCO Alert Pty Ltd | Australia | 100% |
| Performax Alert Pty Ltd | Australia | 100% |
| SIDS Alert Pty Ltd | Australia | 100% |
| VRI Therapeutics & Vaccines Pty Ltd | Australia | 100% and its controlled entities |
| Herbatex Pty Ltd | Australia | 100% |
| Novoceutics Pty Ltd | Australia | 100% |
| Auticoll Pty Ltd | Australia | 100% |
| Candivax Pty Ltd | Australia | 100% |
| Pneumobiotics Pty Ltd | Australia | 100% |
| VRI Biotherapeutics Pty Ltd | Australia | 100% |
| Probendo Pty Ltd | Australia | 100% |
| Mucoprotec Pty Ltd | Australia | 100% |
| Probiall Pty Ltd | Australia | 100% |
| Probiadd Pty Ltd | Australia | 100% |
| VRI Reagents Pty Ltd | Australia | 100% |
| Atheromastat Pty Ltd | Australia | 100% |
| Broncobiotics Pty Ltd | Australia | 100% |
| EV Diagnostics Pty Ltd | Australia | 100% |
| Secril 4 Alert Pty Ltd | Australia | 100% |
| Sphere Animal Health Pty Ltd | Australia | 100% |

All of these subsidiaries meet the criteria of a small proprietary company and consequently are not required to be audited.

# Notes to and Forming Part of the Financial Statements

**for the Year Ended 30 June 2001**

## 25. Segment Information

The company operates in the biotechnology industry in Australia.

The principal development currently being undertaken is research to bring biomedical, diagnostic, therapeutical and vaccine products to market.

## 26. Financial Instruments

### Net Fair Values

The carrying amount of the consolidated entity's financial assets and financial liabilities approximate their fair value.

### Debtors

Debtors are recognised at the amount due. The balance is continually assessed and provision is made for doubtful accounts.

### Accounts Payable

Liabilities are recognised for amounts to be paid in the future for goods and services received on or before the reporting date. Accounts are settled in accordance with the vendor's terms, which are usually between 7 – 30 days.

### Ordinary Shares

Ordinary share capital is recognised at the value of the consideration received by the company. Details of shares issued at balance date are set out in Note 13.

### Amounts Due from Related Entities

All amounts due for related entities are carried at nominal value and a provision for the non recovery of such amounts has been provided for. Interest is not charged on these amounts.

### Investments

Investments are recognised at their original cost.

### Credit Risk

Credit risk on the company's financial assets is the loss that would be recognised if the other parties failed to perform their contractual obligations. The maximum credit risk relating to amounts recognised in the balance sheet is the carrying amount of those assets. The company minimises exposure to credit risk by trading with a substantial number of parties and not having any significant exposure to any individual debtor.

# Notes to and Forming Part of the Financial Statements

**for the Year Ended 30 June 2001**

## 26. Financial Instruments (continued)

### Interest Rate Risk

The consolidated entity's exposure to interest rate risks and the effective interest rates of financial assets recognised at the balance date are as follows:

| Financial Instruments | Floating interest rate | | Fixed interest rate maturing in 1 year or less | | Non-interest bearing | | Total carrying amount per the balance sheet | | Weighted average effective interest rate | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Financial assets** | 2001 $ | 2000 $ | 2001 $ | 2000 $ | 2001 $ | 2000 $ | 2001 $ | 2000 $ | 2001 % | 2000 % |
| Cash | 259,250 | 518,620 | - | - | - | - | 259,250 | 518,620 | 3.7 | 5.0 |
| Receivables | | | | | | | | | | |
| - Commercial bank bills | - | - | 8,950,000 | - | - | - | 8,950,000 | - | 4.9 | - |
| - other | - | - | - | - | 154,450 | 3,157 | 154,450 | 3,157 | - | - |
| Total financial assets | 259,250 | 518,620 | 8,950,000 | - | 154,450 | 3,157 | 9,363,700 | 521,777 | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| **Financial liabilities** | | | | | | | | | | |
| Payables | - | - | - | - | 502,734 | 111,514 | 502,734 | 111,514 | - | - |

# Directors' Declaration

In accordance with a resolution of the Directors of VRI BioMedical Limited, I state that:

1. In the opinion of the directors:

   a) the financial statements and the notes of the company and of the consolidated entity are in accordance with the Corporations Act 2001, including:

      (i) giving a true and fair view of the company's and consolidated entity's financial position as at 30 June 2001 and of their performance for the year ended on that date; and

      (ii) comply with Accounting Standards and Corporations Regulations 2001; and

   b) there are reasonable grounds to believe that the company will be able to pay its debts as and when they become due and payable.

On behalf of the Board

L Ivory
*Chairman*

Perth, 25 September 2001

# Independent Audit Report

ERNST & YOUNG

Central Park
152 St Georges Terrace
Perth WA 6000
Australia

GPO Box M939
Perth WA 6843

Tel 61 8 9429 2222
Fax 61 8 9429 2436

## INDEPENDENT AUDIT REPORT

To the members of VRI Biomedical Limited

**Scope**

We have audited the financial report of VRI Biomedical Limited for the financial year ended 30 June 2001, as set out on pages 36 to 57, including the Directors' Declaration. The financial report includes the financial statements of VRI Biomedical Limited, and the consolidated financial statements of the consolidated entity comprising the company and the entities it controlled at year's end or from time to time during the financial year. The company's directors are responsible for the financial report. We have conducted an independent audit of the financial report in order to express an opinion on it to the members of the company.

Our audit has been conducted in accordance with Australian Auditing Standards to provide reasonable assurance whether the financial report is free of material misstatement. Our procedures included examination, on a test basis, of evidence supporting the amounts and other disclosures in the financial report, and the evaluation of accounting policies and significant accounting estimates. These procedures have been undertaken to form an opinion whether, in all material respects, the financial report is presented fairly in accordance with Accounting Standards, other mandatory professional reporting requirements and statutory requirements, in Australia, so as to present a view which is consistent with our understanding of the company's and the consolidated entity's financial position and performance as represented by the results of their operations and their cash flows.

The audit opinion expressed in this report has been formed on the above basis.

**Audit Opinion**

In our opinion, the financial report of VRI Biomedical Limited is in accordance with:

(a) the Corporations Act 2001 including:

  (i) giving a true and fair view of the company's and consolidated entity's financial position as at 30 June 2001 and of their performance for the year ended on that date; and

  (ii) complying with Accounting Standards and the Corporations Regulations 2001; and

(b) other mandatory professional reporting requirements.

Ernst & Young

G H Meyerowitz
Partner
Perth

Date: 25 September 2001

GHM:SSO:VRI:020

# ASX Additional Information

Additional information required by the Australian Stock Exchange Ltd and not shown elsewhere in this report is as follows. The information is current as at 31 August 2001.

## (a) Distribution of equity securities

The number of shareholders, by size of holding, in each class of share are:

| | Ordinary shares | | Options over ordinary shares | |
|---|---|---|---|---|
| | Number of holders | Number of shares | Number of holders | Number of options |
| 1 – 1,000 | 13 | 10,402 | 36 | 19,812 |
| 1,001 – 5,000 | 374 | 1,355,712 | 736 | 1,885,713 |
| 5,001 – 10,000 | 369 | 3,089,491 | 177 | 1,210,660 |
| 10,001 – 100,000 | 366 | 9,491,194 | 124 | 3,220,937 |
| 100,00 and over | 22 | 44,497,534 | 11 | 17,040,646 |
| | 1,144 | 58,444,333 | 1,084 | 23,377,768 |
| The number of shareholders holding less than a marketable parcel of shares are: | 13 | 10,402 | – | – |

## (b) Twenty largest shareholders

The names of the twenty largest holders of ordinary shares are:

| | | Ordinary shares | |
|---|---|---|---|
| | | Number of shares | Percentage of ordinary shares |
| 1 | Australian Heritage Group Ltd | 10,000,000 | 17.1 |
| 2 | Ivory & Company Pty Ltd (L Ivory) | 9,000,000 | 15.4 |
| 3 | Maktram Pty Ltd (R Clancy) | 9,000,000 | 15.4 |
| 4 | Trivenia Pty Ltd (K Slatyer) | 9,000,000 | 15.4 |
| 5 | AP Barton | 3,000,000 | 5.1 |
| 6 | Perpetual Trustee Company Ltd | 583,300 | 1.0 |
| 7 | National Nominees Ltd | 540,000 | 0.9 |
| 8 | Sunshore Holdings Pty Ltd | 496,300 | 0.9 |
| 9 | JA Cruickshank | 300,000 | 0.5 |
| 10 | Overnight Nominees Pty Ltd | 300,000 | 0.5 |
| 11 | JF Cade | 267,000 | 0.5 |

# ASX Additional Information

(b) Twenty largest shareholders (continued)

| | | Ordinary shares | |
|---|---|---|---|
| | | Number of shares | Percentage of ordinary shares |
| 12 | Yilgumba Nominees Pty Ltd | 232,000 | 0.4 |
| 13 | Vincent Corporation Pty Ltd | 218,500 | 0.4 |
| 14 | Athabasca Pty Ltd | 200,000 | 0.3 |
| 15 | JR & JE Frame | 200,000 | 0.3 |
| 16 | Newport Securities | 200,000 | 0.3 |
| 17 | KC Gower | 181,334 | 0.3 |
| 18 | C Keay | 180,000 | 0.3 |
| 19 | Opus 2 Pty Ltd | 175,000 | 0.3 |
| 20 | NJ Woss | 165,000 | 0.3 |
| | | 44,238,434 | 75.6 |

The names of the twenty largest holders of options over ordinary shares are:

| | | Options | |
|---|---|---|---|
| | | Number of options | Percentage of options |
| 1 | Australian Heritage Group Ltd | 4,000,001 | 17.1 |
| 2 | Ivory & Company Pty Ltd (L Ivory) | 3,600,001 | 15.4 |
| 3 | Maktram Pty Ltd (R Clancy) | 3,600,001 | 15.4 |
| 4 | Trivenia Pty Ltd (K Slatyer) | 3,600,001 | 15.4 |
| 5 | AP Barton | 1,200,001 | 5.1 |
| 6 | Sunshore Holdings Pty Ltd | 260,001 | 1.1 |
| 7 | Perpetual Trustee Company Ltd | 223,840 | 1.0 |
| 8 | Stichting Stroeve Global Custody | 216,000 | 0.9 |
| 9 | Overnight Nominees Pty Ltd | 201,640 | 0.9 |
| 10 | Bow Lane Nominees Pty Ltd | 114,000 | 0.5 |
| 11 | JF Cade | 106,800 | 0.5 |
| 12 | JD & FS Millar | 100,000 | 0.4 |
| 13 | Solomon Ceber Pty Ltd | 100,000 | 0.4 |
| 14 | Yilgumba Nominees Pty Ltd | 92,800 | 0.4 |
| 15 | JR & JE Frame | 80,000 | 0.3 |
| 16 | AR Ramage | 77,000 | 0.3 |
| 17 | KC Gower | 72,535 | 0.3 |
| 18 | Opus 2 Pty Ltd | 70,000 | 0.3 |
| 19 | Howlett & Bailey Pty Ltd | 69,800 | 0.3 |
| 20 | NJ Woss | 66,000 | 0.3 |
| | | 17,850,421 | 76.3 |

# ASX Additional Information

## (c) Substantial shareholders

The names of substantial shareholders who have notified the Company in accordance with section 671B of the Corporations Law are:

| | Number of shares | Number of Options over ordinary shares |
|---|---|---|
| Australian Heritage Group Limited | 10,000,000 | 4,000,001 |
| Ivory & Company Pty Ltd | 9,000,000 | 3,600,001 |
| Trivenia Pty Ltd | 9,000,000 | 3,600,001 |
| Maktram Pty Ltd | 9,000,000 | 3,600,001 |
| AP Barton | 3,000,000 | 1,200,001 |

## (d) Voting rights

All ordinary shares (whether fully paid or not) carry one vote per share without restriction.

## (e) Restricted securities on issue

| | Number of Shares | Number of Options | Date restriction ceases |
|---|---|---|---|
| Ordinary Shares | 66,667 | 26,667 | 20 September 2001 |
| Ordinary Shares | 27,000 | 10,800 | 18 October 2001 |
| Ordinary Shares | 94,165 | 37,666 | 23 October 2001 |
| Ordinary Shares | 113,666 | 45,466 | 31 October 2001 |
| Ordinary Shares | 38,045,097 | 15,218,038 | 14 December 2002 |
| | 38,346,595 | 15,338,637 | |

## (f) Unquoted equity on issue

| Class of security | Number of securities | Number of holders |
|---|---|---|
| Ordinary shares | 38,346,595 | 18 |
| Options over ordinary shares | 15,338,637 | 18 |

# Corporate Governance Statement

The Board is committed to a system of sound corporate governance.

The Board is responsible for the overall governance of VRI BioMedical, including its strategic development as well as the direction and control of its operations. Subject to VRI BioMedical's constitution, the Board deals with the issues of Board composition and selection criteria for directors. The Chairman is responsible to review the performance of the Board to ensure that the Board continues to have the mix of skill and experience necessary for the conduct of the activities of VRI BioMedical.

### *Continuous Disclosure Policy*

VRI BioMedical has adopted a continuous disclosure policy so as to comply with its continuous disclosure obligations. The aims of this policy are to:

- assess, through a continuous disclosure committee, comprising the executive committee, material information and co-ordinate any disclosure or releases to ASX;
- provide an audit trail of the decisions regarding disclosure to substantiate compliance with the Company's continuous disclosure obligations;
- regularly report to the Board on continuous disclosure matters; and
- ensure that employees of VRI BioMedical understand the obligations to bring material information to the attention of the continuous disclosure committee.

### *Share Trading Policy*

VRI BioMedical has adopted a policy that imposes certain restrictions on Directors, senior management and other employees trading in VRI BioMedical securities. The restrictions have been imposed to prevent trading in contravention of the insider trading provisions of the Corporations Law.

The key aspects of the policy are:

- no director, senior manager or employee is allowed to trade securities in VRI BioMedical once the Chairman has issued a notice to that person that trading is to be suspended;
- no employee is allowed to trade securities in VRI BioMedical during the 2 days following an announcement;
- any director, senior manager or employee intending to trade a parcel of securities which exceeds $100,000 in value must give the Chairman one day's prior written notice;
- trading in VRI BioMedical securities without approval is permitted 2 to 30 days after the day of release of VRI's quarterly results if trading has not been suspended by the Chairman or ASX; and
- trading in VRI BioMedical securities is permitted 31 to 60 days after the release of VRI's quarterly results with the prior approval of the Chairman if trading has not been suspended by the Chairman.

# Corporate Governance Statement

*Publications Policy*

The Company has a Publications Policy that governs the release of information regarding the Company's affairs, intellectual property and promotional material.

The objective of this policy is to protect the Company's intellectual property, to prevent the unauthorised release of statements that could be challenged as misleading or deceptive and to maintain confidentiality pursuant to the Company's policy governing confidential information. (Confidentiality provisions bind all directors and staff as well as contractors/consultants).

No information about the Company's intellectual property or any promotional material can be published either verbally or in writing without firstly being approved by the Executive Committee.

VRI BioMedical has established corporate governance committees to critically review the operations of the Company as set out below:

*Audit and Risk Management Committee*

This committee comprises Professor Cade (Chairman), Mr Baxter and Mr Slatyer. John Frame is the secretary to the Committee. Where considered appropriate, VRI BioMedical's external auditors and management are invited to attend meetings.

The duties of this committee include:

- to be the focal point of communication between the Board, management and the external auditors;
- to recommend and supervise the engagement of the external auditors and monitor the auditors performance;
- to review the effectiveness of management information and other systems of internal control;
- to review all areas of significant financial risk and arrangements in place to contain those to acceptable levels;
- to review significant transactions that are not a normal part of the Company's business;
- to review the year end and interim financial information and ASX reporting statements;
- to monitor the internal controls and accounting compliance with the Corporations Law, Listing Rules and to review external audit reports and ensure prompt remedial action;
- to review VRI BioMedical's financial statements (including interim reports) and accounting procedures;
- to review and approve the Company's Research and Development protocols;
- to review the ethics committee applications and monitor the human trial results ensuring proper process is applied; and
- to regularly review Intellectual Property and patent management processes.

During the first half of the 2001 calendar year the Audit and Risk management Committee undertook a risk management review of the Company's Research and Development operations. The Committee engaged an independent consultant, to assist in this review process.

# Corporate Governance Statement

*Remuneration Committee*

This committee is made up of Mr Baxter (Chairman), Mr Slatyer and Professor Cade. John Frame is Secretary to the Committee.

The remuneration committee is responsible for reviewing and making recommendations to the Board regarding the compensation arrangements for the directors and senior management of VRI BioMedical (including ESOP and other benefit plans). It will also be responsible for considering general remuneration policies and superannuation requirements.

The level of the non-executive directors' fees are to be reviewed annually by the Board following a review by the Chairman but will take into consideration additional time required for involvement in various committees.

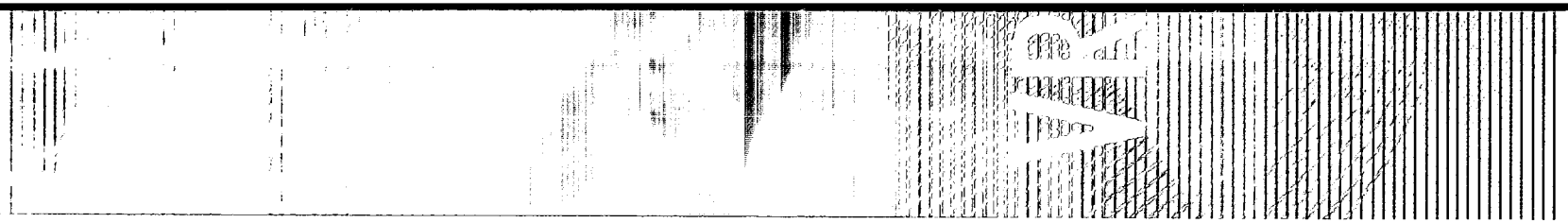
The committee review the recruitment and termination practices and policies of the Company.

During the early part of 2001, the Remuneration Committee engaged Mr. Ian Cordiner of Cordiner King Hever to conduct a review of the director and senior executive remuneration and make recommendations regarding these matters. The Committee forwarded the report to the Board for consideration and actioning as appropriate.

*Executive Committee*

The Company has an Executive Committee made up of Leon Ivory, Professor Clancy and John Frame. The Committee's purpose is to advise Leon Ivory as Chief Executive Officer on strategic and policy matters, to conduct regular review of operational matters as well as internal controls and ethical standards.

Dr Comans who has been appointed as Chief Operating Officer effective 17th September 2001 is also a member of this Committee.



VRI
BioMedical

Corporate Head Office
Level 11, BGC Centre, 28 the Esplanade Perth WA 6000
Telephone (08) 9321 3655 Facsimile (08) 9321 3650
Webpage www.vribiomedical.com