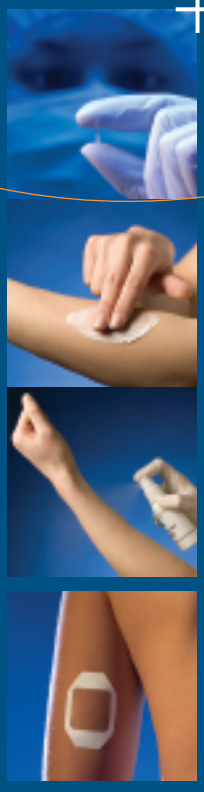
# 2004

annual report to shareholders

milestones



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## Notice of meeting

The EpiTan Limited Annual General Meeting will be held at:

Stamford Plaza Hotel
111 Little Collins Street Melbourne 3000
On Friday 1 October, 2004 commencing at 10.00am in the Edinburgh Room on Level 1.

01 Company profile
02 Chairman and managing director's report
04 Directors
06 Management and consultants
08 Informative section
12 Review of operations
Clinical development
Pharmaceutical development
New business development
Pharmaceutical products

18 Statutory financial section
*Corporate governance statement*
*Directors' report*
*Financial report and statements*
*Directors' declaration*
*Independent audit report*
*ASX additional information*

Corporate directory

# company profile

**EpiTan Limited is a Melbourne-based specialty pharmaceutical company with a focus on prescription dermatology products. Its leading drug candidate is Melanotan® which stimulates the body to make melanin. Melanin, which causes a tan, is known to protect the body from skin damage as a result of sunburn. Sunburn is a known prime cause of skin cancer. Simply, Melanotan induces a protective tan without the need to expose the skin to harmful levels of ultra-violet (UV) radiation. EpiTan recently acquired Linotar® (eczema), Exorex® (psoriasis) and Zindaclin® (acne) - and is currently evaluating the acquisition or in-licensing of other dermatology-based products to add to its portfolio.**

*Melanotan profile*

Melanotan has completed a Phase II clinical trial in Australia which demonstrated the drug increases melanin content in the skin by up to 100% and reduces sunburn injury by up to 50% in fair-skinned volunteers. This represents a significant breakthrough for people most at risk of sunburn injury and skin cancer. Melanotan will now undergo clinical studies in Europe and the USA. Future trials will assess its potential as a therapy for UV-associated skin disorders such as polymorphous light eruption (PMLE).

Melanotan will be delivered by a user-friendly and biodegradable sustained-release implant, administered by a single injection. Transdermal formulations are also being tested.

An independent report commissioned by the company confirmed that there are three potentially lucrative markets for Melanotan. Firstly, the prophylactic market includes those populations that do not tan well and seek additional protection from UV damage. Secondly, the therapeutic market consists of patients with UV-associated skin diseases or disorders for which Melanotan may provide a clinical benefit and, finally, the cosmetic market comprises those people who want a tan, but not specifically for health reasons.

# executive chairman and managing directors' report

Dear Shareholder,

I am pleased to report to you that EpiTan made significant progress during the year.

We continued to achieve further major milestones in the development of our leading drug candidate Melanotan. Also, just after the end of the financial year, the company acquired three prescription dermatology products, two of which, Linotar and Exorex, are already registered and generating sales in Australia. The third, Zindaclin, has been submitted to the regulatory authorities and is expected to be launched in 2005.

You may recall in prior years' reports, I have made mention of our aim to broaden the company's portfolio by seeking other late stage drug development projects and in-licensing products to secure a solid pipeline of current and future revenues. We are now well on the way to achieving that goal with the careful acquisition of products that fit our profile and rigorous financial criteria.
We are currently evaluating the acquisition or in-licensing of further products to add to our newly acquired portfolio. These acquisitions will build our sales revenue ahead of the commercialisation of Melanotan which we confidently expect to be a major driver in our future growth when launched. It is exciting to record that independent estimates of Melanotan's global annual sales in the first two years after launch exceed $1.5 billion. Sales for Australia and New Zealand, included in this estimate, approximate $70 million.

## Review of operations

*Highlights for the year*

- Phase II clinical trial for sunburn injury completed with results exceeding expectations;
- Phase I/II dose escalation clinical trial for the long acting implant showing better than expected efficacy;
- Topical formulations of Melanotan in preclinical studies;
- Continued collaborative research with Monash University (Melbourne) and the Institute of Medical and Veterinary Science (IMVS) based in Adelaide;
- Signed a collaborative agreement with pSiMedica Limited (UK), to develop a new liquid-based sustained release formulation for Melanotan incorporating pSivida's BioSilicon™ nanotechnology to be delivered subcutaneously;
- Additional $8.9 million capital raised from existing and new shareholders;
- Filed a provisional patent from data obtained in the sunburn injury clinical trial;
- Market capitalisation increased to $105.2 million (2003: $24.5 million);
- EpiTan's share price performance was +241% (2003: +145%) representing one of the best performing biotech stocks of 2003/2004, rising from 27 cents to 92 cents at 30 June 2004; an increase of 241%.

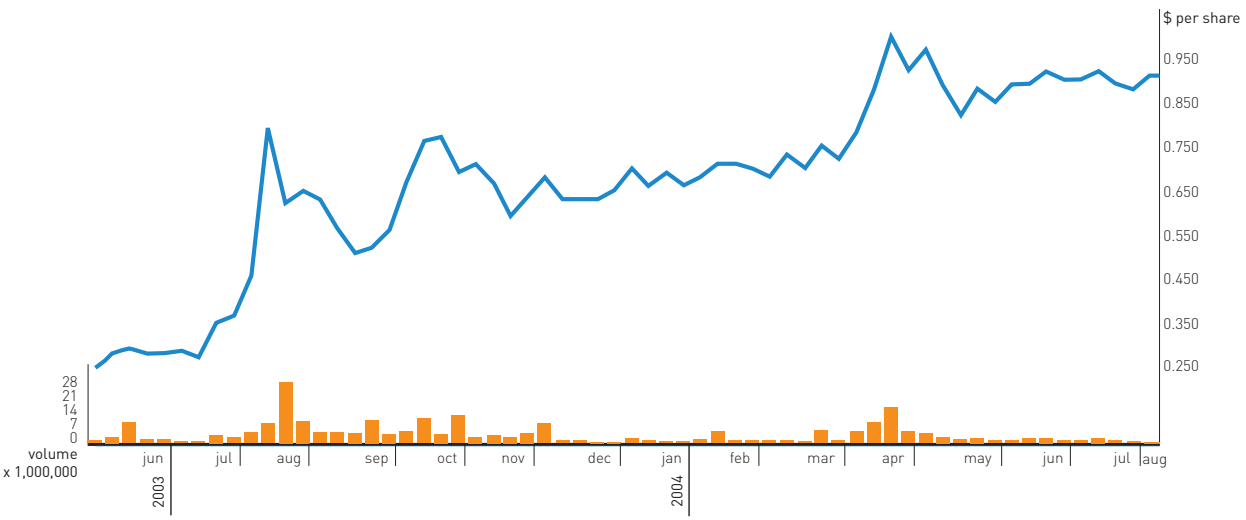
*Highlights since 30 June 2004*

- Two prescription dermatology products, Linotar and Exorex, acquired from TransDermal Pharmaceuticals Pty Ltd in July;
- In-licensed Zindaclin from UK based Strakan International Limited in July;
- Successful placement of 10.5 million shares raising $7.98 million in August (including 6.7m unlisted options);
- Filed a provisional patent from data obtained in the sustained release clinical trial.

*Financial*

At the beginning of the year the company's cash resources were $2.6 million. During the year the company spent $7.4 million, including $5.5 million on clinical trials and drug formulation research and development, earned $344,000 in bank interest and received $285,000 in GST refunds. A total of $8.9 million was raised in fresh capital during the year from both the exercise of listed options in July and the placement of 14.5 million shares to institutional and professional investors in August. At the end of the financial year, the company's financial resources amounted to $5.7 million.

In August 2004, EpiTan increased its cash resources by $7.98 million following the placement of 10.5 million shares to two offshore institutional investors. At the same time EpiTan issued 6,667,362m unlisted options exercisable over 3 years at A$1.03 which, if exercised, would result in a further cash injection of A$6.87m. These resources will enable the company to continue the development of Melanotan, actively pursue the acquisition or in-licensing of prescription dermatology products and carry out further research into new indications for Melanotan during the coming year.



*Clinical trials*

The final results from our definitive sunburn clinical trial, performed at Sydney's Royal Prince Alfred Hospital and the Royal Adelaide Hospital were released in November. The trial's key objective of demonstrating the effectiveness of Melanotan on reducing sunburn injury by increasing melanin density was achieved. For the first time results showed that, in fair-skinned volunteers, a drug could achieve a 50% reduction in sunburn injury following exposure to UV radiation. A major component of sunburn injury is DNA damage to skin cells.

Key findings from the data were:

- A highly significant increase in skin melanin was seen in Melanotan-treated volunteers compared to those given the placebo, at all body sites measured.
- Melanin density increases, as high as 100% percent, were observed in fairer skinned volunteers, in particular.
- Sunburn injury, as induced with solar-simulated UV radiation, was reduced by more than 50% in the fair-skinned volunteers.

EpiTan is obviously delighted with these results, as there is no ethical or over the counter (OTC) product available to prevent sunburn injury other than sunscreens. We know from the results of studies recently published in the UK and Australia that some sunscreens may fall short of the protection expected. Now, by using Melanotan, it has been shown that fair-skinned people can reduce sunburn injury by as much as 50%. This is a major advance, and when used in conjunction with existing skin protection methods, should ensure that people have the ability to protect themselves better from the harmful effects of UV radiation.

In November 2003 the implant trial started at Q-Pharm, which is based at the Clive Berghofer Cancer Research Centre at Royal Brisbane Hospital in Queensland.

The key objective of this trial is to confirm an optimal dose for the implant as well as the usual safety compliance and efficacy.

In February 2004 we announced better than expected efficacy in this implant dose escalation trial. The first six volunteers, who received the two lowest levels of the melanin-producing drug Melanotan, quickly demonstrated a substantial increase in melanin levels. After 60 days the volunteers still had a profound natural tan. We were very pleased that the implants worked so well and so quickly in these first volunteers. We didn't anticipate that so little drug would be needed to achieve increased melanin levels. In February 2004 we had to order new implants with lower concentrations of Melanotan.

In June 2004 this trial resumed with a new, significantly smaller solid injectable. This implant will be more acceptable to the individual as well as being very cost effective.

The remaining volunteers will receive escalating doses of the new sustained-release formulation over the coming months, with results expected in late 2004.

The results of this study will determine the final commercial formulation for Melanotan.

*Drug delivery formulations*

It is important that EpiTan continues to investigate the development of additional delivery mechanisms. Two major developments were made during the year.

Firstly, following the better-than-expected efficacy of the previous larger implant announced in February 2004, a new batch of much smaller implants containing considerably less drug were developed in five months.

The solid injectable formulation is made from the same material as the earlier implant and is therefore known to be safe and reliable. The implant is biodegradable and does not have to be removed at the end of the treatment. It is expected that Melanotan will be first launched onto the market with the implant.

Secondly, we can report encouraging progress with development of topical formulations. In due course, the successful development of a topical formulation will offer patients and doctors the choice of an alternative user-friendly and non-invasive delivery for Melanotan.

*Intellectual property*

EpiTan has a comprehensive family of patents covering all major jurisdictions. As an ongoing focus and as a consequence of the successful results from the clinical trial program, two important new provisional patent applications have been filed. The first was filed in November 2003. This patent encompasses the pharmacogenomic data obtained from the sunburn injury trial performed in 2003. The second was filed in August 2004 and encompasses the data obtained from the Phase I/II sustained release clinical trial. The granting of these patents would result in EpiTan extending its patent protection of Melanotan by 20 years.

*Investor relations*

Publicity this year on the Melanotan story, has like the previous year, been very positive. Media interest throughout the world continues to be attracted to this drug and its potential applications for skin protection and therapies.

The story has been covered widely in domestic and international newspapers, TV, radio and professional publications, and extensive interviews have been given by company executives.

In July, EpiTan established a Level One American Depositary Receipt (ADR) program. The code for the EpiTan ADR is EPTNY and the Cusip number is 29427H205. The Bank of New York was appointed as the depositary bank for the ADR program. Each ADR represents 10 ordinary shares of EpiTan as traded on the ASX.

During the year, EpiTan has maintained its program of continuous disclosure to its investors and financial markets. The company also continued its policy of close association with the financial community by undertaking regular presentation briefing programs with institutions and brokers including visits to existing and prospective investors in London and New York. These initiatives will be stepped up as the Melanotan project gains momentum in the coming year.

*Outlook*

The company will continue to develop its unique melanogenesis platform technology through its leading drug candidate Melanotan.

Towards the end of 2004 the company expects to expand its clinical trials into Europe and USA. These will be commenced as soon as we have determined the final commercial formulation for Melanotan from the current study in Queensland.

As we have previously reported, EpiTan is in discussions with larger American and European pharmaceutical companies to consider collaborative partnerships. Such a relationship would include funding for the Phase III trials and commercialisation stages. These discussions are active and progressing well around the licensing and co-promotional rights to Melanotan for North America and Europe. EpiTan expects to retain the full rights to Australia and New Zealand.

EpiTan ended the year strongly thanks to the efforts of its directors, management, staff and consultants who continue to contribute above and beyond the call of normal duty. I thank them wholeheartedly for their efforts.

Our shareholder base has increased considerably over the past year and we now have some 3,670 shareholders. In addition as a result of widespread publicity and public interest in EpiTan and our leading drug candidate Melanotan, we have over 10,000 users registered on our website either as potential trial volunteers or seeking to receive regular updates on our progress. We put a lot of effort into maintaining contact with all stakeholders both via our website which undergoes regular updates and company presentations where appropriate.

The 2004 year was another period of major progress. Melanotan has a potentially huge market and we are looking forward to next year with even greater enthusiasm. Your continued and loyal support is, as always, appreciated.

**DR WAYNE MILLEN**
Executive Chairman & Managing Director

# directors

**MR STANLEY MCLIESH**
BEd
Non executive Director

Mr McLiesh has extensive experience in commercialising pharmaceutical products internationally. Formerly General Manager, Pharmaceuticals at CSL Limited, he was closely involved in the transition of CSL from government ownership through corporatisation to a highly successful listed company. While at CSL, Mr McLiesh brokered numerous in-licensing agreements with international companies which enabled CSL to expand into new markets profitably. The rapid acceleration of growth in sales and marketing associated with this in-license activity resulted in the establishment by Mr McLiesh of new sales and marketing teams. He has also been closely involved in a number of merger and acquisition negotiations; the establishment of partnerships and collaborative relationships; quality control, manufacturing and the negotiation of supply agreements for CSL's export products to international markets. Mr McLiesh's considerable experience in the international pharmaceutical industry will facilitate EpiTan's expansion strategies. Mr McLiesh is a Non executive Director of Unitract Limited (ASX:UNI).

**DR HELMER AGERSBORG**
BS PhD
Non executive Deputy Chairman

Dr Agersborg received a PhD in Physiology from the University of Tennessee in 1957 and shortly after was appointed to the position of Clinical Physiologist at Wyeth Laboratories in Pennsylvania, US. In 1975, he was promoted to Vice-President, Research and Development with responsibility for research, chemical, pharmaceutical and biological development, quality assurance and regulatory affairs. In 1985, he was given the additional responsibility for clinical research and made Senior Vice- President. In 1987, American Home Products began to merge its international, Ayerst and Ives and AH Robins research and development activities into one unit, Wyeth-Ayerst Research, an organisation of approximately 3000 people. Dr Agersborg was made President, Wyeth-Ayerst Research in 1987. During his distinguished forty years in the pharmaceutical industry companies under his direction had more than 50 new drug applications approved in the US and many marketing applications approved outside the US. Following his retirement from Wyeth-Ayerst in 1990, Dr Agersborg became involved in a series of start-up pharmaceutical development companies. Dr Agersborg is currently Chairman and President of MelanoTan Corp, President of Afferon Corp and director of Virxsys Corporation, all pharmaceutical companies. Dr Agersborg contributes broad international pharmaceutical development experience at the highest level to the company.

**DR WAYNE MILLEN**
BSc (Hons) PhD FRACI C CHEM AFAIM
Executive Chairman and Managing Director

Dr Millen is the founding Managing Director of EpiTan Limited. He has a PhD in chemistry and biochemistry from the University of Western Australia and is a Chartered Chemist with extensive experience over 35 years operating his own commercial enterprises. In 1967, as a Fulbright scholar, Dr Millen undertook biochemical research in the Molecular Biology Institute at the University of California, Los Angeles, with Nobel Prize laureate Dr Paul Boyer. In 1970, he established his own consultancy business, the Pilbara Group, for the testing and assessment of biological, environmental and mineral materials, which grew to be the largest organisation of its kind in the Australasian region. In 1983, Dr Millen moved into the area of venture and development capital investment with an emphasis on companies involved in technological innovation. He has maintained this focus to the present time and has been the lead investor and strategist in several private and public companies. Dr Millen's scientific and business experience, along with his proven entrepreneurship has been instrumental in maximising corporate opportunities for EpiTan.

**DR TERRY WINTERS**
BSc PhD
Non executive Director

Dr Winters is a director of four private US based companies: MelanoTan Corp, licensor of EpiTan's technology; Amplimed, an oncology drug development company; Afferon Corp, developing vanilloid drugs for incontinence and Vital Therapies, developing the first human cell-based liver assist device. Dr Winters is also a Special Limited Partner of Valley Ventures, a $130 million venture capital fund based in Scottsdale, Arizona. Dr Winters was formerly an experimental chemist and licensing manager with Goodyear Tyre & Rubber Co. in Ohio and then licensing manager with Diamond Shamrock and Vice-President of DS Ventures, investing in life science projects. In 1983, he co-founded, and is a General Partner of Columbine Venture Fund which has invested over $125 million in life science and technology companies in the western US. From the Columbine investments, successful companies have been Orthologic Corp, CollaGenex Pharmaceuticals, Nanophase Technologies, Curis, Neogen (all NASDAQ quoted) and Microgenics. Dr Winters' understanding of US financial markets, particularly capital raising and Nasdaq listing brings an international perspective to the company's global corporate planning.

# management and consultants



*From top to bottom: Iain Kirkwood, Dr Stuart Humphrey, Michael Kleinig, Chris Rossidis*

**IAIN KIRKWOOD** MA(Hons)(Oxon) FCPA FFTP CA MAICD
Chief Financial Officer

Iain brings to EpiTan extensive financial, commercial and business/strategic experience. With a successful career spanning over more than 25 years in Australia, Britain and the USA he has held a range of senior financial positions with major public companies including F.H. Faulding & Co. Limited (CFO), Santos Limited and Pilkington plc. He is a Chartered Accountant, CPA, former President of the Finance and Treasury Association of Australia and a member of the Institute of Company Directors. Iain has been integral in the development of the company's financial and commercial profile as the Melanotan project moves towards maturity. He has been actively involved in marketing EpiTan to the investment community in Australia, Europe and USA. Iain is also a Non executive Director of Medical Developments International Limited (ASX:MVP).

**DR STUART HUMPHREY** BSc (Hons) PhD
Manager Clinical Development

Stuart brings to the company extensive experience in the management of scientific and clinical development projects within multinational pharmaceutical environments. His clinical development and regulatory background in the field of oncology has been instrumental in progressing the company's clinical trial program. Stuart has an Honours degree in Biochemistry from the University of Liverpool, UK and a Doctorate of Philosophy from the University of Auckland with 34 years experience in research and pharmaceutical project management. He has held the positions of Regional Operations Manager at Omnicare Clinical Research, a large international Clinical Research Organisation and Regulatory Affairs Manager and Manager Scientific Clinical Development with Bristol-Myers Squibb in Australia and New Zealand.

Stuart manages all clinical trials including the responsibility for recruiting investigating sites and writing trial protocols. He is responsible for filing all necessary documentation with the relevant regulators.

**MICHAEL KLEINIG** BAppSc (Chem/Bio)
Manager Pharmaceutical & New Business Development

Michael spent 15 years as a Senior Research Scientist at CSL Limited where he was working in research and development in both the Pharmaceutical and Bioplasma divisions. He graduated from Swinburne Institute of Technology with a double major in Applied Chemistry and Biochemistry.

At EpiTan, his primary responsibilities include investigating the best method(s) of delivery for Melanotan, securing a suitable commercial scale manufacturer of the synthetic peptide and seeking a collaborative partnership with a larger pharmaceutical company. In addition Michael is involved in marketing EpiTan to both the financial community and the broader pharmaceutical world.

Michael has extensive knowledge in the fields of process development (from research scale through to commercial scale), project management, immunology and protein chemistry.

**CHRIS ROSSIDIS** BSc
Manager Pharmaceutical Products

Chris has broad experience of the pharmaceutical industry after spending 15 years in sales and marketing roles at Eli Lilly, Glaxo Welcome and latterly CSL. As CSL's Business Development Manager, he was responsible for supporting CSL's growth through identifying and evaluating new prescription medicine business.

Chris is responsible for developing a prescription sales and marketing operation in the dermatology field in Australia and New Zealand. Chris' primary focus is to evaluate local Australian dermatology product acquisitions and alliances and overseas product in-licensing opportunities.

## consultants

**DR PERRY ROBINS** MD
Medical Advisory Consultant

Dr Perry Robins is an eminent New York-based skin cancer specialist. He is Professor of Dermatology and Chief of the Mohs Micrographic Surgery Unit at New York University Medical Center. Dr Robins has joined EpiTan as a Medical Advisory Consultant to facilitate the expansion of EpiTan's clinical trials into the USA and Europe.

Dr Robins has practiced medicine for over 35 years, treating more than 40,000 skin cancer patients. As an accomplished educator in his field, he has trained sixty doctors from around the world who are now leaders in dermatologic and skin cancer care, and he has lectured in 34 countries. At present, he performs more than 1,000 surgical procedures annually and conducts training workshops for his peers in advanced techniques of dermatologic surgery.

Dr Robins is founder and president of the Skin Cancer Foundation (www.skincancer.org), an international organisation dedicated to skin cancer research and education. The advisory board and medical councils of the Skin Cancer Foundation comprise more than 144 leading international physicians who are distinguished members of the scientific and medical communities and members of the business and professional sectors.

Dr Robins is also the founder/president of the International Society of Dermatologic Surgery, founder/former president of the American College of Mohs Micrographic Surgery, and former president of the American Society of Dermatologic Surgery.

**DR ELLA TOOMBS** MD
Regulatory Advisory Consultant

Dr Toombs was a dermatology specialist with the US Food and Drug Administrations (FDA) for 13 years.

Dr Toombs is the Washington DC representative on the advisory board of the American Academy of Dermatology and a member of the National Medical Association and American Association of Pharmaceutical Physicians.

She is currently a consultant in private practice specialising in aesthetic dermatology.

**PROFESSOR ROBERT DORR** BS MS PhD RPh
Scientific Consultant

Dr Robert Dorr is co-inventor of the Melanotan technology and was the principal investigator in Melanotan's preclinical and clinical studies performed to date in the US. He continues to have an active involvement in the Melanotan project as a consultant. Dr Dorr has a PhD from the College of Medicine at the University of Arizona, and is currently the Professor of Pharmacology and Director of the Pharmacology Research Program at the Arizona Cancer Center. He is a registered pharmacist in Arizona and California, holds twelve US patents for anticancer drugs and drug delivery devices, and has authored over 150 scientific articles. His expertise includes new drug formulation, animal models of cancer and toxicity assessment and clinical pharmacokinetics of new agents. He is a member of the American Association for Cancer Research, the Southwest Oncology Group and the International Society of Oncology Pharmacy Practice, in which he received the Outstanding Biotechnology Award in 1999.

*Why do we tan?*
*What is melanin?*
*Is a tan dangerous?*
*Is melanin protective?*
*Different skin colours*
*Why Melanotan?*
*Melanotan as a pharmacogenomic drug*
*Do sunscreens offer protection?*
*Are solariums dangerous?*

# why melanotan is pushing back the frontiers of tanning

*Why do we tan?*

Tanning is the body's response to ultraviolet (UV) radiation and subsequent skin damage. There are two types of UV radiation that penetrate the earth's atmosphere - UVB and UVA. UVB causes burning to the top layer of the skin which gives the tell-tale red appearance of sunburn called "erythema". Exposure to UVB also increases the risk of basal cell carcinoma and squamous cell carcinoma, two forms of non-melanoma skin cancer.

UVA has a longer wavelength and penetrates deeper, reaching the basal level of the skin where special tanning cells known as melanocytes are found. Exposure to UVA contributes to skin ageing and there is increasing evidence that this increases the risk of malignant melanoma, the most dangerous form of skin cancer.

The body's response to damage caused by either UVB or UVA is to release a hormone called alpha-Melanocyte Stimulating Hormone ( $\alpha$ MSH) from adjacent cells. $\alpha$ MSH binds to specific receptors on the melanocytes to trigger the cell to produce the dark pigment melanin. An increased level of melanin following exposure to sunlight is commonly referred to as "a tan". For many Caucasians however, the melanocyte receptors evolved to become inactive over time due, in part, to living in the far northern latitudes. Their ability to tan without burning is reduced.

*What is melanin?*

Melanin is the natural substance that gives colour (pigment) to skin. Eumelanin and phaeomelanin are the two classes of melanin present in human skin. Eumelanin is a dark brown to black pigment which protects against UV radiation. Phaeomelanin is a red-yellow pigment and is the form of melanin associated most closely with the potential to sunburn easily and to develop skin cancer. Individuals with light coloured skin and brown, blond or red hair tend to have a significant amount of phaeomelanin in their skin whereas darker skinned and black haired individuals have predominantly eumelanin. The incidence of skin cancers in these darker skinned individuals is lower than in the fair skinned population, and the rationale for tanning is to develop a barrier to UV radiation to minimise the chances of developing skin damage and ongoing skin cancers.

*Is a tan dangerous?*

Historically, a tan has been considered "dangerous" since research uncovered the link between UV exposure and skin cancer. Over the past several decades anti-cancer councils around the world have promoted measures such as using sunscreen and protective clothing to reduce the incidence of skin cancer as a result of over exposure to UV radiation. Repeated sunburn injury is a known precursor to skin cancer (the most prevalent of all cancers).

Until Melanotan, there was no such thing as a "safe" tan.

*Is melanin protective?*

Epidemiological studies have clearly associated increased levels of melanin with reduced incidences of skin cancer.[1]

Melanin protects the skin from both UVA and UVB radiation. In response to UV exposure, melanin granules disperse into the epidermal skin cells and form a shield around the cell's nucleus. This protects the cell's vital nuclear DNA from being further damaged by UV light. In fair-skinned people it may take up to weeks, if at all, to develop a protective level of melanin and during this period they may sustain further sunburn. The person develops a tan, but only after significant damage has been done to the skin cells.

*Different skin colours*

Populations have evolved particular skin colours in order to better survive in certain environments. Dark skin was an essential human trait at least 1.5 million years ago when our ancestors lived in the more UV-exposed equatorial habitats. However, as later ancestors migrated northwards into more temperate climatic zones, their tropical skin tones posed a problem for the vital production of vitamin D. Sunlight penetrating skin spurs production of vitamin D, essential for absorbing the calcium needed to build and support the skeleton. The UV-protection afforded to dark skin by high melanin levels now became a barrier to this vitamin D synthesis. Lighter skin then evolved in higher latitudes to ensure that sufficient UV light could be absorbed by the skin. Humans living in the middle latitudes or more temperate zones - most of the United States and southern Europe - needed moderately pigmented skin but an excellent ability to change their skin tone through tanning. They could increase melanin efficiently during summer but then lighten their tan during winter to accommodate both the protective demand for melanin to reduce skin damage and the reduced levels required to maximise vitamin D production.

[1] Cress RD, Holly EA., Incidence of cutaneous melanoma among non-Hispanic whites, Hispanics, Asians and blacks: an analysis of California cancer registry data, 1988-93. Cancer Causes Control 8(2):246-52 1997

Typically, Caucasian people have from 0.5% to 5% constitutive skin melanin (starting melanin density)[2]. Those fair skinned individuals with 1% or less cutaneous melanin usually burn in the sun and do not tan - these are referred to as Fitzpatrick skin type I. Fitzpatrick skin types II and III have melanin densities in their skin ranging between 1% and 3% and type IV skin, which always tans and rarely burns, contains more than 3% melanin. Dwyer et al[2] recently concluded from measurements of cutaneous melanin density at the upper inner arm of Caucasian men living in Australia that those with 0-1% melanin were associated with approximately 7 times greater relative risk of malignant melanoma or basal cell carcinoma than men with > 3% melanin.

*Why Melanotan?*

Melanotan is significantly more potent than the naturally occurring $\alpha$ MSH and it binds onto the melanocyte receptors, stimulating the cells that produce melanin. Importantly, when Melanotan initiates melanogenesis (melanin production), eumelanin, the most protective type of melanin, is preferentially made.

Clinical trials of Melanotan have demonstrated that fair-skinned people will benefit most from Melanotan. Melanotan is most effective for Fitzpatrick types I and II who are most at risk of developing skin cancer because they are fair, tan poorly and burn easily. Melanotan has been proven to increase the melanin levels of these skin types by up to 100% so that they become equivalent to skin types III and IV (tan well and burn mildly or rarely). This is the first time that a drug has been demonstrated to induce a protective level of melanin in people who normally cannot make significant amounts of melanin.

*Melanotan as a pharmacogenomic drug*

Pharmacogenomics can be defined as "the study of the interaction of an individual's genetic makeup and response to a drug". Pharmacogenomics can be employed in drug development for a number of diseases and disorders in order to identify those individuals most likely to respond to a certain therapy. This new era of personalised medicine is being perceived to be the future in the pharmaceutical world, certainly in cancer therapy.

Clinical trials conducted by EpiTan, have shown that pharmacogenomic analysis could be applied to Melanotan, particularly for prophylactic (preventative) use. There are 35 genetic variants on the Melanocortin 1 receptor (MC1-R). Subjects possessing certain combinations of these genetic variants are more susceptible to skin cancer. A focused genotype study is planned to determine which specific alleles, that are related to poor melanin production, will respond to Melanotan.

This relatively new field of drug development or "personalised medicine" is set to revolutionise the way patients are diagnosed and drugs are prescribed. Knowing in advance who will benefit from Melanotan will facilitate a more simple, efficient and effective process for doctors and patients.

*Do sunscreens offer protection?*

Sunscreens offer a measure of protection against UV radiation. Sunscreen sun protection factors (SPFs) are measured by timing how long skin covered with sunscreen takes to show initial signs of burning compared to uncovered skin. For example, applying sunscreen with an SPF of 15 should mean that it will take 15 times longer for skin to show signs of burning (assuming the recommended amount of sunscreen is applied).

Because SPF factors only take into account burning times, they only apply to UVB rays.

Broader spectrum sunscreens have been developed in an attempt to protect against both UVB and UVA radiation. A recent study by RAFT[3] (Restoration of Appearance and Function Trust) in the UK found, however, that most sunscreens fail to stop harmful UVA which is now considered to be a major factor in causing melanoma, the most significant form of skin cancer.

The danger from UVA rays has been given further backing by Australian research that was published in March 2004[4]. In this study, the researchers found that UVA rays caused DNA damage to the cells deep within the skin. It is this layer of cells that regenerates our skin and it is feared that damage to the DNA of these cells may increase a person's risk of developing melanoma.

However in spite of the extensive campaigns by health authorities and doctors, many people especially the young choose to ignore the health message in pursuit of the "fashionable tan". Compliance is a serious issue as people often fail to apply the recommended amount of sunscreen and also fail to reapply as regularly as necessary because it washes/sweats off.

[2] Dwyer T, Blizzard L, Ashbolt R, Plumb J, Berwick M & Stankovich JM. Cutaneous melanin density of Caucasians measured by spectrophotometry and risk of malignant melanoma, basal cell carcinoma, and squamous cell carcinoma of the skin. Am J Epidemiol 155: 614-621, 2002.

[3] Haywood R, Wardman P, Sanders R & Linge C. Sunscreens Inadequately Protect Against Ultraviolet-A-Induced Free Radicals in Skin: Implications for Skin Aging and Melanoma J. Invest. Dermatol 121: 862-868 2003

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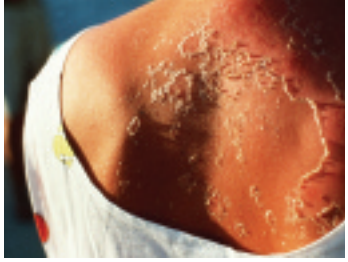

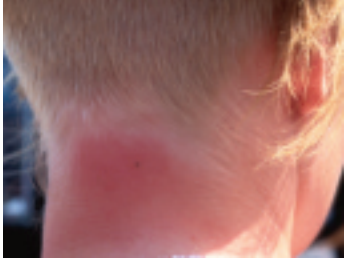

*Repeated sunburn injury is a known precursor to skin cancer.*

*Are solariums dangerous?*

In October 2003 a new study involving more than 100,000 Scandinavian women showed what researchers say is the strongest evidence to date that artificial tanning with UV light can cause malignant melanoma. They found that baking under artificial lamps as little as once a month can boost the risk of this deadly form of skin cancer by 1.5 times[5].

At the same time, researchers in Dartmouth, UK, reported that people who had ever visited a tanning salon were 2.5 times more likely to later get squamous cell skin cancer and 1.5 times more likely to develop basal cell skin cancer than those who hadn't visited tanning salons.[6]

The two most common sources of UV radiation for humans are the sun and tanning salons, and more than 90% of skin cancers among Caucasian people occur on areas regularly exposed to UV radiation.

Tanning salons predominately use UVA light to avoid "sunburn".

In the USA, the American Academy of Dermatology estimates greater than one million Americans are visiting tanning salons every day. Other figures quote that in 2001, there was approximately 28 million visits made to 25,000 solariums.

*Sunburn and skin cancer - a summary*

In the USA in 1999, there were more than 65 million reported cases of sunburn in the USA.[7] The consequence of this, namely the high exposure of the population to UV radiation, is that more than 1 million cases of common skin cancers occur annually in the USA and it is expected that approximately 53,000 new cases melanoma will be diagnosed this year.[8] The increasing awareness that UV exposure is the primary cause of skin damage and skin cancer drives the global industry for sun care products. In the US alone, the total sales for 2000 were calculated to be US$483 million.[9]

Skin cancer has the highest incidence rate of any cancer in the world today. Between 2 and 3 million non-melanoma skin cancers, e.g. basal cell and squamous cell carcinomas, are diagnosed each year around the world. Approximately 130,000 malignant melanomas occur globally each year, substantially contributing to mortality rates in fair-skinned populations. An estimated 66,000 deaths occur annually from melanoma and other skin cancers.[10]

Australia has the highest rate of skin cancer in the world. One out of every two Australians will develop some form of skin cancer during their lives. On average, 740,000 new cases of skin cancer are diagnosed in Australia every year. The cost to the Federal Government every year is in excess of $300 million.[11]

"The incidence of and mortality of skin cancer have increased exponentially during the past several decades and every year the figure mounts" according to The Skin Cancer Foundation (USA).[12]

EpiTan's prime focus is to develop Melanotan as an ethical drug to reduce the incidence of skin damage. When Melanotan is launched, it is also likely to have significant appeal as a "cosmetic" drug because it will satisfy the desire of people to "look good". Consequently it is also highly likely to change current sunbathing and solarium habits.

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**Results of EpiTan's clinical trial program during the year have exceeded expectations. The effectiveness of Melanotan in increasing skin melanin levels and reducing sunburn injury was significantly greater than anticipated. Against the background of this success in Australia, EpiTan will now expand its clinical trial program into Europe and the USA.**

To date, two clinical trials have been completed in Australia (during 2001-2003) under GCP (Good Clinical Practice) conditions. These studies (EP001 and EP002) demonstrated the safety and efficacy of Melanotan and its ability to significantly increase skin melanin levels, particularly in at-risk groups. In addition, a dose escalation study (EP004) of a sustained release injectable form of Melanotan commenced in November 2003 and has led to the development of a new, miniature implant.

In 2004-2005 a number of studies are planned for the USA, Europe and Australia. These studies are to identify the commercial dose for the sustained release injectable and prepare the way for Phase III trials. The dose-finding study is expected to be completed in late 2004.

### Studies in 2003-2004

*Phase II sunburn study (EP002) - completed*

61 subjects were injected with Melanotan on a daily basis (at 0.16mg/kg/day) for up to 30 days (20 subjects received placebo injections).

The results of this study showed that fair-skinned people - who traditionally burn the most in the sun and are therefore at greatest risk of developing skin cancer - benefited most from Melanotan.

The trial was designed to determine how Melanotan could reduce the degree and toxicity of sunburn in healthy volunteers exposed to UV light, both before and after a regime of the drug Results showed that:

- There was a highly significant increase in skin melanin in Melanotan-treated volunteers.
- Fair-skinned people (Fitzpatrick skin types I & II) recorded increases in melanin of up to 100% in some skin areas.
- Sunburn injury was reduced by more than 50% in Fitzpatrick skin types I & II volunteers.
- People vastly underestimated their natural skin-protection levels. Only 7% of volunteers thought they had Fitzpatrick skin type I (always burns/ never tans). The real number was 36%.

These positive results have clearly shown the potential of developing what is in effect an "injectable sunscreen" that will be especially beneficial to those people with fair skin who are most at risk of sunburn injury and therefore of developing skin cancers.

Results of this study have been submitted for publication in respected peer review journals.

*Phase I/II Dose escalation study (EP004) - in progress*

Following the completion of the company's second study in Australia, EpiTan progressed to a third study using, for the first time, a sustained release delivery formulation for Melanotan. This formulation will be the initial commercialised product.

The dose escalation study was designed to assess the pharmacokinetics and tanning effect in healthy adults and was performed at Q-Pharm commencing in November 2003.

The implant was injected into the abdomen through a small incision and changes in skin tanning were measured by reflectance spectrophotometry. Three subjects, received a 20mg dose and a further three subjects received a 40 mg dose of Melanotan. Both groups experienced a rapid and highly significant increase in melanin density. The effect of the drug in this formulation was far greater than expected and a new miniaturised injectable form of Melanotan has now been manufactured. This implant can be delivered as a simple injection.

The dose finding study using the new implant recommenced in June at Q-Pharm in Queensland and is expected to be completed in late 2004.

### Future studies

EpiTan plans an active clinical program to maintain momentum in Australia and will expand its clinical program into the USA and Europe.

EpiTan has opened negotiations for an Investigational New Drug (IND) program in the USA with the Food and Drug Administration (FDA). Meetings with the European Medicines Agency (EMEA) are also planned to gain approval to conduct trials in Europe.

Using the newly developed controlled release formulation, further Phase II studies are planned to establish the safety and degree of tanning in Caucasian subjects with either genetic susceptibility to sunburn and skin cancer or some form of UV associated skin disease or disorder (such as polymorphous light eruption [PMLE] or solar urticaria).

*Phase II Genotype study on MC1-R variant alleles (EP003)*

It is now recognised that the human Melanocortin 1 receptor (MC1-R) gene, which is central to the tanning response of the melanocytes following UV irradiation, has a number of gene variants that are associated with an increased risk of skin cancer.

A genotype study to investigate this is planned to be carried out at the Queensland Institute of Medical Research (QIMR) under the direction of Professor Adèle Green. Professor Green's group has already published results showing an increased risk of skin cancer in individuals who have abnormal melanocyte receptors in their skin. The intention of this study is to compare the efficacy of Melanotan in individuals with normal and variant genotypes.

*Phase II studies to define appropriate endpoints*

Once the dose of the new solid injectable formulation of Melanotan has been finalised, the pharmacokinetics and safety of this slow-release solid dose injectable form of Melanotan administered subcutaneously to healthy men and women with fair skin (Fitzpatrick skin types I & II only) will be assessed. Skin melanin will be monitored over an extended (three month) period and its effectiveness at reducing UV irradiation effects on the skin will be assessed before and after 1, 2 and 3 months of treatment by calculating the erythema dose-response curve and minimal erythema dose (MED). Suitable endpoints to be considered for further studies in a Phase III program will be:

(a) photoprotection provided by Melanotan against UVA radiation,

(b) increase in sun protection factor (SPF) using the slope of the erythema dose-response curve; and,

(c) reduction in DNA-related cell damage markers in the basal stem cell layer of epidermis subsequent to 3xMED irradiation.

*UV-associated skin diseases and disorders*

Other studies to define suitable indications for Melanotan will be performed in the USA or Europe where conditions such as Polymorphous Light Eruption (PMLE) are prevalent. Between 10 and 20% of the population in the USA and Europe suffer from PMLE.

These studies will determine the individuals to whom Melanotan can be of most benefit. Subjects will receive the implant and pigmentation will be measured one and two months later using the non-invasive spectrophotometric measurement for melanin. The efficacy endpoint will be the reduction in symptoms associated with the photosensitive disorder eg. sunburn, erythematous and/or blistered patches/plaques etc. The first study is planned to begin in Europe to coincide with the winter period in the Northern Hemisphere.

*Phase III studies*

The studies in Phase II will be enlarged to produce a pivotal, randomised global study (USA, Europe and Australasia) which will be a double blind, Phase III, placebo-controlled trial of a single subcutaneous implant in patients with fair skin.

**STUART HUMPHREY** Manager Clinical Development

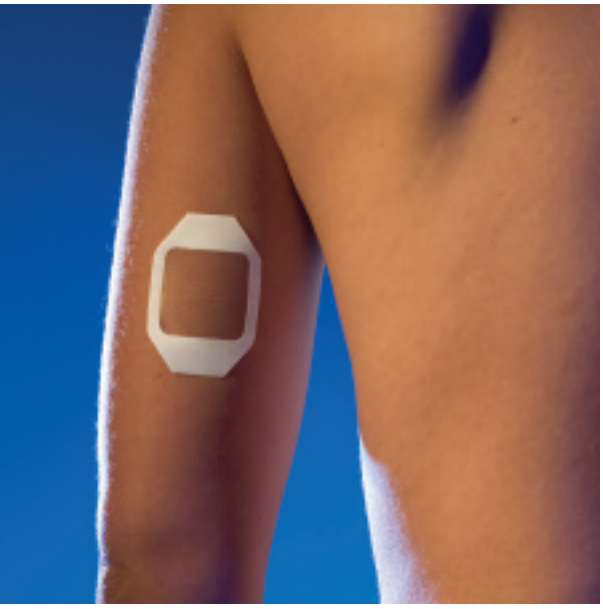
It was another exciting year in the advancement of Melanotan towards the commercial product. In addition to the major milestones passed in the clinic, a series of key advancements were also achieved in the pharmaceutical development area.

## Drug delivery formulations

*Subcutaneous*

The sustained release implant formulation developed for the dose escalation clinical trial (EP004) proved to be too efficacious at the lowest level when tested in humans. This unexpected result meant the sustained release formulation had to be redeveloped with much less drug. In collaboration with Southern Research Institute (Birmingham, Alabama), a new, much smaller solid injectable was developed and manufactured in only five months. The new implants were ready in June for use in the "recommenced" trial at the Queensland Institute of Medical Research (QIMR). The results of this clinical trial will determine the commercial dosage to allow the company to plan large scale production in time for market launch.

Drug delivery formulations



The new formulation is a small implant designed to be placed under the skin via a single injection, and is made of the same material that has been used for many years in "self-dissolving" stitches. It is therefore known to be safe and reliable and as the implant is totally biodegradable it does not have to be removed at the end of the treatment. By this means, Melanotan is slowly released into the body over a period of about 20 days so that the subjects participating in following clinical trials will need only one injection to develop the appropriate levels of melanin. Similar implants, such as Zoladex® (AstraZeneca) for the treatment of prostate cancer, have already been approved for use in Australian and worldwide markets.

EpiTan is also collaborating with pSiMedica, a subsidiary of pSivida Ltd (ASX:PSD), a Perth-based nanotechnology company, to develop an alternative liquid sustained release dosage form. Results from the proof of principle studies are expected later in 2004. If successful, this would enable the delivery of a liquid sustained release Melanotan formulation via a small gauge needle.

*Topical*

During the year EpiTan has been rapidly progressing its development of a topical delivery of Melanotan. To achieve this, EpiTan has been working closely in collaboration with CollaGenex and Thomas Sköld (Restoraderm® technology), TransDermal Technologies, Inc. (TDS® technology), Monash University (Melbourne) and the Institute of Medical & Veterinary Sciences (IMVS) in Adelaide.

EpiTan expects to file additional patent applications arising from the results of its research and clinical trial program, to further strengthen and consolidate its patent portfolio.

*Drug manufacture*

A pilot-scale batch of Melanotan was manufactured under cGMP (code of Good Manufacturing Practice) specifications by its European supplier. This material has been used in the research studies and has been incorporated into the sustained release formulation for use in clinical trials.

The manufacture of this successful pilot-scale batch opens the way for the drug to be produced in commercial batch sizes, preparing for the market launch of Melanotan.

To ensure a reliable supply of Melanotan, EpiTan has continued discussions with other leading peptide manufacturers. This will allow for commercial scale amounts of the drug to be produced under cGMP specifications at the most commercially competitive price.

*Research studies*

EpiTan has continued its close relationships with Australian researchers during the year. Last year, EpiTan announced the signing of collaborative agreements with Monash University Melbourne and the Institute of Medical and Veterinary Science (IMVS) Adelaide. Work performed under these collaborations included research towards the development of new cheaper and more sensitive assays for the testing of Melanotan in preclinical and clinical samples, the establishment of efficacy models for the testing of potential drug formulations, development of a bioassay for measuring the biological activity of Melanotan, as well as investigating candidate topical formulations.

# new business development

Following the release of successful Phase II clinical trial results the company has commenced discussions with several larger pharmaceutical companies regarding the future joint development of the Melanotan project. These discussions are active and progressing well.

**Melanotan, a market perspective**

In May 2004, EpiTan commissioned PharmaVentures Limited, an international business development consultancy, to conduct an independent valuation of the worldwide markets for Melanotan.

PhamaVentures identified three alternative markets for Melanotan, namely prophylactic, therapeutic and cosmetic. Their evaluation was limited to the first generation product, namely the solid injectable sustained release formulation used in EpiTan's current clinical trial program.

*Prophylactic market*

PharmaVentures describes the prophylactic market as the market deemed to include those populations who do not tan well and are at an increased risk of developing skin cancer. These populations wish to be protected from sunburn and damaging UV radiation, which may increase their risk of getting skin cancer. This market encompasses the Caucasian population with Fitzpatrick Skin Type I and II who are at most risk of developing skin cancer but does not include those patients with a therapeutic application (covered later) who could be treated with Melanotan.

With regard to the prophylactic market, skin cancer is a major global health issue affecting millions of lives and costing economies billions of dollars in treatment and loss of production.

Rates of incidence of melanoma are continuing to increase without a plateau in the European Community countries England, Wales, Ireland, Belgium, Denmark, Germany, the Netherlands, France, Italy, Spain and Greece.[13] In Germany alone the incidence of skin cancer has increased 20-fold since 1930 according to the European Society of Skin Cancer Prevention.[14]

*Therapeutic market*

The therapeutic market for Melanotan is described by PharmaVentures as the market that comprises diseases or syndromes wherein the product might provide a therapeutic benefit to the afflicted individuals. These people have UV associated skin diseases and disorders such as PMLE, psoriasis, rosacea, solar urticaria, porphyria, vitiligo or albinism.

PMLE is estimated to effect about 10% of the population of the USA. Interestingly, this figure rises to an estimated 21% for the population of Sweden.[15] According to IMS Health, the world psoriasis therapy market was worth in excess of $500 million in 2000. This was a 10.4% increase from 1999.[16] Vitiligo alone, a skin disease causing the loss of pigmentation, is estimated to affect 2-4 million Americans with treatment costs at close to $6000 per patient over 120 treatments in a 1-1.5 year period.[17]

*Cosmetic market*

PharmaVentures outlines the cosmetic market for Melanotan to consist of people who wish to have a tan to "look good" and not specifically for health reasons. This encompasses the population currently using tanning salons and sunless tanning products. There is also the untapped population that do not use tanning salons due to the safety risk, or tanning lotions due to the inconvenience, but if an alternative was available, they would embrace it to gain a "healthy looking" tan.

The popularity of tanning is escalating despite the global increasing awareness of skin cancer. Surveys show that while more people are aware of the dangers of unshielded exposure to UV radiation, the desire to be fashionable, look good and "feel healthy" outweighs their health concerns. This is evidenced by the substantial growth of the indoor tanning salon (solarium) industry particularly in northern latitude countries.

The market for tanning in salons in the US is estimated at US$2 billion dollars per annum[18] with a further US$100 million spent on self-tanning products.[19]

In Europe, Germany has more than 25,000 tanning salons with an annual turnover of US$1.5 billion,[20] Italy is estimated to have approximately 4000 tanning salons[21] and the UK market is flooded with more than 20,000 places to tan.[22]

Importantly, EpiTan's prime focus on the unmet medical need for an ethical drug to reduce the incidence of skin damage can also tap into the sunless tanning market. If the use of Melanotan satisfies the desire of this market that wish to just "look good", it will also drastically lower the need for the user to attend the indoor tanning salon and/or sunbathe thus also reducing their harmful exposure to UV radiation. Subsequently this could eventually lower the incidences of skin cancer, currently estimated at greater than two-fold in people who visit tanning salons.

Following their cosmetic market estimation, PharmaVentures state that they believe that there is also a huge latent market for cosmetic application in those individuals who do not use artificial tanning products at present. They equate this latent market to the increased markets following approval of drugs such as Botox® and Viagra®.

It was also concluded by PharmaVentures that if a systemic topical formulation was developed, this would be expected to expand the prophylactic and cosmetic markets considerably due to the non-invasive method of administration.

**MICHAEL KLEINIG** Manager Pharmaceutical & New Business Development

A new pharmaceutical products business was established towards the end of the financial year. EpiTan has a specific focus to acquire prescription dermatology products from overseas and domestically to build a specialised pharmaceutical company in Australia and New Zealand. There are ambitious plans to grow rapidly as more products are acquired.

During the year, negotiations progressed with a number of companies for product acquisitions or licensing. Just after the year end, two products were acquired from Transdermal Pharmaceuticals Pty Limited Australia - Linotar for the treatment of eczema and Exorex for the treatment of psoriasis. These two products are already registered and generating sales in Australia. The potential growth in a combined eczema and psoriasis market is valued at over $10 million dollars.

EpiTan has also licensed the Australian and New Zealand rights from UK-based Strakan Pharmaceuticals for Zindaclin, a unique once a day clindamycin based cream for the treatment of acne. The registration dossier for Zindaclin has been submitted to the Therapeutic Goods Administration and launch is expected in 2005. The size of the anti-acne market in Australia is approximately $12 million dollars.

Other acquisition and in-licensing opportunities are being actively pursued to drive future growth in sales building up to the launch of Melanotan with its expected sales of $70 million over the first two years (Source: PharmaVentures Research Report).

EpiTan has recognised a unique opportunity in Australia to develop the only ASX listed pharmaceutical company with a focus on prescription dermatology products.

**CHRIS ROSSIDIS** Manager Pharmaceutical Products

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# financial report for year ended 30 june 2004

## index


19 corporate governance statement
21 directors' report
24 statement of financial performance
25 statement of financial position
26 statement of cash flows
27 notes to the financial statements
40 directors' declaration
41 independent audit report
43 asx additonal information

# corporate governance statement

This statement outlines the main corporate governance principles and practices of EpiTan Limited. Unless stated otherwise, directors are of the opinion that these comply, in all material respects with the ASX Corporate Governance Council's "Principles of Good Corporate Governance and Best Practice Recommendations" (ASX Principles) released in March 2003.

The company is committed to the highest standards of corporate governance and a protocol was documented and adopted by the Board in August 2000 in the period leading up to the company's listing on ASX. Corporate governance is regularly reviewed and following the release of ASX Principles, the Board has updated the framework of original documentation.

The following 10 sections below summarise EpiTan's compliance with the ASX Principles:

**Principle 1 – lay solid foundations for management and oversight**

There is a clear segregation of duties between the Board and management. The Board sets strategic direction and a policy framework which management then work within to manage the day-to-day business.

**Principle 2 - structure the board to add value**

The current directors of the company and details of skills, experience, qualifications, tenure and attendances at meetings are included in the section headed 'company particulars'.

Subject to the requirement of the Corporations Act that a public company must have at least three directors (two of whom must be resident in Australia), the Board determines its size and composition.

The Board has a Remuneration and Nomination Committee. It is chaired by Mr McLiesh who is an independent director. The other members of this Committee comprise the remainder of the Board. The Committee does not have, and does not intend to adopt, any formal guidelines concerning Board size or composition other than to ensure that at all times there are either members of the Board or secondees available to the Board with appropriate industry and financial expertise. Further, as a general rule, appointments will only be made to the Board where appropriate to complement the existing skill base of the Board.

Recommendation 2.1 of the ASX guidelines requires that a majority of the Board should be independent directors. For the purpose of determining independence, the Board has had regard to the ASX guidelines. It has also resolved not to set specific materiality thresholds, preferring instead to consider all relationships on a case by case basis, having regard to the accounting standards' approach to materiality and accepted commercial practice.

While the Board has a policy of complying with Recommendation 2.1 and an expectation that all directors will bring their independent views and judgement to the Board, Mr McLiesh is the only independent director. Therefore, EpiTan does not, at this time, comply with Recommendation 2.1. However, for companies of the current size and status of EpiTan to comply with Recommendation 2.1 is not easy. To do so, EpiTan would either need to add significantly to the number of directors on its Board, which cannot be justified, or ignore the qualifications, specific technical experience and contribution made by two of its directors, Dr Agersborg and Dr Winters, simply because they represent a substantial shareholder of EpiTan. This would be despite the fact that their contributions have been of significant value to EpiTan in its current stage of development. In all the circumstances, EpiTan considers its Board size and composition to be appropriate.

Recommendation 2.2 of the ASX guidelines requires the chairperson be an independent director. Further, Recommendation 2.3 requires that the same individual should not exercise the roles of chairperson and Chief Executive Officer. The role of Chairman of the Board was assumed by Dr Millen (the Chief Executive Officer) on the resignation of the former (non-executive) incumbent during 2002. Dr Millen is the founder of EpiTan and an entity associated with him continues to be the largest single shareholder of EpiTan. Despite Dr Millen holding both offices, the Board believes that is entirely appropriate for EpiTan given the composition of its Board and its current size, status and circumstances. Further, the Board does not believe that the appointment of, and continued performance by, Dr Millen of the roles of chairperson and Chief Executive Officer has had any adverse effect on the conduct of the affairs of EpiTan or the representation of the interests of the shareholders at Board level.

Further, to obviate any potential for conflicts of interest, whether actual or perceived, arising from the above Board and management structures, the Board has adopted very strict policies concerning disclosure of interests and conflicts of interest. These policies are in addition to the requirements of the Corporations Act / ASX Listing Rules.

Recommendations 2.4 and 2.5 of the ASX guidelines relate to the establishment of a nomination committee and to reporting to shareholders on matters relevant to Principle 2 of the ASX Corporate Governance guidelines. EpiTan's Remuneration and Nomination Committee and reporting are consistent with those recommendations.

The Board has a policy of enabling directors to seek independent professional advice at the company's expense. This advice, if appropriate, will be shared with other directors. While it is the policy of EpiTan that the Executive Chairman will generally review (in advance) the estimated costs of obtaining this advice, that policy exists to ensure the reasonableness of the cost. It does not exist to impede the seeking of advice.

The Board is currently considering its size and composition and the introduction of a formal performance assessment process for its directors. Further advice on these issues will be communicated to the shareholders as appropriate.

**Principle 3 – promote ethical and responsible decision-making**

The company recognises the need for directors and employees to observe the highest standards of behaviour and business ethics when engaging in corporate activity.

The company intends to maintain a reputation for integrity. The Board has adopted a Code of Ethics which sets out the principles and standards with which all officers and employees are expected to comply in the performance of their respective functions.

A key element of that Code is the requirement that officers and employees act in accordance with the law and with the highest standards of propriety. The Code and its implementation are to be reviewed each year.

*Dealing in company shares*

All employees in the company receive advice regarding the requirements of the Corporations Act 2001 with regard to trading in the shares of the company. In addition to the requirements of the Corporations Act 2001, the company has a policy that prohibits all directors and employees from trading in shares in the company whilst in possession of non-public or "inside" information.

Any transaction conducted by directors in shares of the company is notified to the Australian Stock Exchange (ASX). Each director has entered into an agreement with the company to provide information to allow the company to notify the ASX of any share transactions within five business days.

**Principle 4 – safeguard integrity in financial reporting**

The current Board comprises the members of the Audit Committee and the Chairman is Dr Winters. Dr Millen is a non-voting member. The principal functions of the Audit Committee include reviewing and making recommendations to the Board regarding:

- assisting the Board in the discharge of its responsibilities in respect of the preparation of the company's financial statements and the company's internal controls;
- recommending to the Board nominees for appointment as external auditors;
- providing a line of communications between the Board and the external auditors; and
- examining the external auditors evaluation of internal controls and management's response.

The Audit Committee meets at least twice per year and the Chief Financial Officer is invited to attend all meetings.

The Audit Committee is responsible for the terms of the appointment. The external auditor is invited to attend all Audit Committee meetings during the year. Although the appointment of the external auditor is reviewed regularly by the Audit Committee, it is anticipated that the audit engagement partner will be rotated every 5 years.

The auditors do not prepare the primary accounting records nor are they involved in company decision making. The technical expertise of the auditors is called upon from time to time to assist the directors in discharging various statutory responsibilities.

**Principle 5 – make timely and balanced disclosure**

The company fully supports the continuous disclosure regime in Australia. Continuous disclosure is a standard agenda item at all Board meetings and the company makes regular announcements to the market on commercial activities, which may have a material influence on the share price.

Presentations that are made to analysts or investors are posted on the company's website. If the presentations contain information that has not been in the public domain, and that would have a material effect on the share price, the presentation is sent to the ASX prior to the presentation being made.

All managers in the company receive advice on continuous disclosure and are aware of the company's obligations with regard to continuous disclosure.

**Principle 6 – respect the rights of shareholders**

Communication with shareholders is of critical importance to the company. The annual report, half-year report and annual general meeting are all important communications forums. The company welcomes questions from shareholders at any time and these are answered within the confines of information that is not market sensitive or already is in the public domain. Also, all announcements made by the company to the ASX (except disclosures of a compliance nature) are posted on the company's website.

The external auditor attends the annual general meeting and is available to answer any questions with regard to the conduct of the audit and their report.

**Principle 7 – recognise and manage risk**

The Audit Committee as part of its charter considers the management of risk. The company has carried out a formal risk review. Risks identified have appropriate actions developed or mitigating circumstances documented. It is the Board's intention that the risk review is formally assessed and updated on an annual basis. The Committee considers on an annual basis the insurance policies the company has in place. The Chief Financial Officer, on an annual basis, reports on the internal control environment within the company and is responsible for immediately alerting the Committee if any material breakdowns in internal control occur.

**Principle 8 – encourage enhanced performance**

The Board will develop during the next financial year a process for the performance evaluation of the Board and its Committees.

**Principle 9 – remunerate fairly and responsibly**

The Remuneration and Nomination Committee constitutes the full Board and is chaired by Mr McLiesh. It is responsible for determining the compensation arrangements for directors, the Chief Executive Officer and other executives. This Committee is also responsible for the nomination of directors and reviewing the balance, nature and experience required of directors to properly fulfil its duties.

The Committee assesses the appropriateness of the nature and amount of remuneration of these officers at least annually by reference to relevant employment market conditions and by the engagement of a specialist remuneration consultant with experience in the healthcare and biotechnology industries. The overall objective is to ensure the engagement and retention of the highest quality board and executive team for the benefit of all stakeholders.

The Committee, assisted by the external consultants, seeks to link the nature and amount of executive directors and officers compensation to the company's financial and operations performance. All directors and executives are eligible to participate in the company's option plan. In addition, executives may be entitled to annual bonuses payable at the discretion of the Committee for specific performance achievements which have demonstrably contributed to an increase in shareholder value.

**Principle 10 – recognise the ligitimate interests of stakeholders**

The Code of Ethics formally documents the company's approach to all stakeholders. The company expects all its employees to act with the utmost integrity with all stakeholders. The company does not make political donations, but does participate in a number of industry bodies that promote and support the industry the company works in.

# directors' report

The directors of the Board present their report on the company and its controlled entity for the financial year ended 30 June 2004 and the independent Audit Report thereon.

## DIRECTORS

The names of directors in office at any time during or since the end of the year are set out below. Each director was in office for the whole of the financial year unless stated otherwise:

Dr W.A. Millen (Executive Chairman)
Dr H.P.K. Agersborg (Deputy Chairman)
Dr T.E. Winters
Mr S.R. McLiesh

Directors have been in office since the start of the financial year to the date of this report unless otherwise stated.

**Information on directors**

Dr Wayne A. Millen *Executive Chairman and Managing Director*
Age: 63
Qualifications: BSc(Hons) PhD FRACI C CHEM FAus IMM AFAIM

Experience: Dr Millen is the founding Managing Director of EpiTan Limited.

He has a PhD in chemistry and biochemistry from the University of Western Australia and is a Chartered Chemist with extensive experience over 35 years operating his own commercial enterprises.

Dr Millen has extensive experience in venture and development capital investment with an emphasis on companies involved in technological innovation and has been the lead investor and strategist in several private and public companies.

He has considerable experience in establishing and managing start-up enterprises and brings to the company operational skills embracing corporate, technological and marketing disciplines.

Interest in shares and options: 17,726,375 ordinary shares.

Dr Helmer P.K. Agersborg
*Non executive Deputy Chairman*
Age: 75
Qualifications: BSc PhD

Experience: Dr Agersborg is Chairman and President of MelanoTan Corp, President of Afferon Corp and director of Virxsys Corporation, all pharmaceutical companies. He has been President of Wyeth-Ayerst Research.

During his distinguished forty years in the pharmaceutical industry, more than 50 new drug applications were approved in the United States, countless marketing applications were approved outside the United States and innumerable IND's were accepted around the world by companies under his direction.

Dr Agersborg contributes broad international pharmaceutical development experience at the highest level to the company.

Interest in shares and options: 750,000 ordinary shares and 250,000 options to acquire ordinary shares.

Dr Terry E. Winters
*Non executive Director*
Age: 62
Qualifications: BSc PhD

Experience: Dr Winters is a director of four private US based companies and a Special Limited Partner of Valley Ventures, a $50 million venture capital fund based in Scottsdale, Arizona.

In 1983, he co-founded, and is a General Partner of, Columbine Venture Fund which has invested over $125 million in life science and technology companies in the western USA.

From the Columbine investments, successful companies have been Orthologic Corp, CollaGenex Pharmaceuticals, Nanophase Technologies, Curis, Neogen (all NASDAQ quoted) and Microgenics.

Interest in shares and options: 16,065,415 ordinary shares and 250,000 options to acquire ordinary shares.

Mr Stanley Roy McLiesh
*Non executive Director*
Age: 67
Qualifications: BEd

Experience: Mr McLiesh has extensive experience in commercialising pharmaceutical products internationally. Formerly General Manager, Pharmaceuticals at CSL Limited, he was closely involved in the transition of CSL from government ownership to corporatisation to a highly successful listed company.

While at CSL, Mr McLiesh brokered numerous in-licensing arrangement with international companies which enabled CSL to expand into new markets profitably. Mr McLiesh has considerable experience in the international pharmaceutical industry.

Interest in shares and options: 1,000,000 options to acquire ordinary shares.

## MEETING OF DIRECTORS

The following table summarises the number of and attendance at all meetings of directors during the financial year.

| Director | Board | | Audit Committee (1) | | Remuneration & Nomination Committee (2) | | Other (3) | |
|---|---|---|---|---|---|---|---|---|
| | A | B | A | B | A | B | A | B |
| Dr W.A. Millen | 7 | 7 | 2 | 2 | 3 | 3 | 1 | 1 |
| Dr H.P.K. Agersborg | 7 | 7 | 2 | 2 | 3 | 3 | 1 | – |
| Dr T.E. Winters | 7 | 7 | 2 | 2 | 3 | 3 | 1 | – |
| Mr S.R. McLiesh | 7 | 7 | 2 | 2 | 3 | 3 | 1 | 1 |

**Column A** –indicates the number of meetings held during the period the Director was a member of the Board and/or Board Committee.

**Column B** - indicates the number of meetings attended during the period the Director was a member of the Board and/or Board Committee.

1 The Audit Committee is chaired by T.E. Winters. Dr W.A. Millen is a member of the Committee but is not entitled to vote.

2 The Remuneration and Nomination Committee is chaired by Mr S.R McLiesh.

3 Other was a special committee of the Board to approve accounts.

## PRINCIPAL ACTIVITY

The principal activity of the consolidated entity during the financial year was to further develop, Melanotan, the company's leading drug candidate in the field of melanogenesis, the process whereby melanin is produced in the body.

## OPERATING RESULTS

The consolidated loss of the consolidated entity after providing for income tax amounted to $7,589,730 (2003 - $3,976,770).

## DIVIDENDS PAID OR RECOMMENDED

No dividends were paid or declared during the financial year.

## REVIEW OF OPERATIONS

The review of operations is set out in detail on pages 12 to 17 of this Annual Report.

**Highlights for the year**

- Phase II clinical trial for sunburn injury completed with results exceeding expectations;
- Phase I/II dose escalation clinical trial for the long acting implant showing better than expected efficacy;
- Topical formulations of Melanotan in preclinical studies;
- Continued collaborative research with Monash University (Melbourne) and the Institute of Medical and Veterinary Science (IMVS) based in Adelaide;
- Signed a collaborative agreement with pSiMedica Limited (UK), to develop a new liquid-based sustained release formulation for Melanotan incorporating pSivida's BioSilicon™ nanotechnology to be delivered subcutaneously;
- Additional $8.9 million capital raised from existing and new shareholders;
- Filed a provisional patent from data obtained in the sunburn injury clinical trial;
- Market capitalisation increased to $105.2 million (2003: $24.5 million);
- EpiTan's share price performance was +241% (2003: +145%) representing one of the best performing biotech stocks of 2003/2004, rising from 27 cents to 92 cents at 30 June 2004; an increase of 241%.

**Financial**

At the beginning of the year the consolidated entity's cash resources were $2,611,853. During the year the consolidated entity spent $7,944,965 including $5,538,639 on clinical trials and drug formulation research and development, earned $355,235 in bank interest and received $285,351 in GST refunds. During the year a total of $8,913,516 was raised in fresh capital from the placement of 14,500,000 shares and the exercise of options. At the end of the financial year, the consolidated entity's cash resources amounted to $5,480,367.

## SIGNIFICANT CHANGES IN THE STATE OF AFFAIRS

There have been no significant changes in the state of affairs.

## SIGNIFICANT EVENTS AFTER THE BALANCE DATE

Directors are not aware of any significant events that may have occurred subsequent to balance date, except:

- A placement of 10,500,000 ordinary shares at $0.76 each and the granting of 6,667,362 unlisted options with an exercise price of $1.03 expiring August 2007 was completed on 11 August 2004 to institutional and sophisticated investors pursuant to s.708 of the Corporations Act. Total proceeds amounted to $7,980,000 before expenses;
- Acquired two prescription dermatology products, Linotar and Exorex from TransDermal Pharmaceuticals Pty Ltd in July;
- Entered into an agreement to in-license Zindaclin from UK based Strakan International Limited on 16 July;
- Filed a provisional patent from data obtained in the sustained release trial in August.

## LIKELY DEVELOPMENTS AND EXPECTED RESULTS

The directors anticipate that the company will continue its clinical trial and drug development program.

## ENVIRONMENTAL REGULATION AND PERFORMANCE

The consolidated entity's operations are not regulated by any significant environmental regulation under a law of the Commonwealth or of a State or Territory.

## DIRECTORS' AND EXECUTIVE OFFICERS' EMOLUMENTS

The emoluments of each director are as follows:

| | Salary $ | Cash Bonus $ | Superannuation Contributions $ | Allowances $ | Options $ | Total $ |
|---|---|---|---|---|---|---|
| Dr W.A. Millen | 229,611 | 50,000 | 25,390 | 12,446 | – | 317,447 |
| Dr H.P.K Agersborg | 36,666 | – | – | – | 33,638 | 70,304 |
| Dr T.E. Winters | 36,666 | – | – | – | 33,638 | 70,304 |
| Mr S.R. McLiesh | 37,982 | – | 3,562 | – | 62,762 | 104,306 |

The emoluments of each executive officer are as follows:

| | | | | | | |
|---|---|---|---|---|---|---|
| Mr I.M. Kirkwood | 97,546 | 5,000 | 14,229 | – | 50,887 | 167,662 |

The company has no other executive officers.

# directors' report continued

### INDEMNIFICATION AND INSURANCE OF DIRECTORS AND OFFICERS

During or since the end of the financial year the company has given an indemnity or entered an agreement to indemnify, or paid or agreed to pay insurance premiums as follows.

The company has paid premiums to insure each of the directors against liabilities for costs and expenses incurred by them in defending any legal proceedings arising of their conducts while acting in the capacity of director of the company, other than conduct involving wilful breach of duty in relation to the company. The amount of the premium was $90,737.

### EMPLOYEES

The consolidated entity employed 8 employees as at 30 June 2004 (2003: 6 employees).

### DIRECTORS' BENEFITS AND INTEREST IN CONTRACTS

Since the end of the pervious financial year, no director has received or become entitled to receive a benefit (other than a benefit included in the total amount of emoluments received or due and receivable by directors shown in the financial statements), because of a contract that the director or a firm of which the director is a member, or an entity in which the director has a substantial interest has made with Epitan Limited or a controlled entity.

### SHARE OPTIONS

At the date of this report, unissued ordinary shares of the company under option are:

| Expiry date | Exercise price | Number of options |
|---|---|---|
| 30 September 2005 | $0.30 / share | 141,556 |
| 31 March 2006 | $0.30 / share | 750,000 |
| 3 April 2006 | $0.10 / share | 750,000 |
| 22 October 2006 | $0.10 / share | 1,300,000 |
| 1 January 2008 | $0.66 / share | 375,000 |
| 2 February 2008 | $0.16 / share | 750,000 |
| 13 June 2008 | $0.29 / share | 500,000 |
| 18 April 2009 | $0.87 / share | 300,000 |
| 31 December 2007 | $0.74 / share | 750,000 |

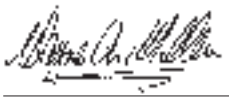
During the year ended 30 June 2004, 8,509,253 shares were issued as a result of the exercise of unlisted options.

### PROCEEDINGS ON BEHALF OF THE COMPANY

No person has applied for leave of Court to bring proceedings on behalf of the company or intervene in any proceedings to which the company is party for the purpose of taking responsibility on behalf of the company for all or any part of those proceedings.

The company was not party to any such proceedings during the year.

Signed in accordance with a resolution of the Board of directors:



**W.A. MILLEN** DIRECTOR
Dated this 17 day of August, 2004.

# statement of financial performance

The accompanying notes form part of these financial statements

| | | Consolidated | | EpiTan Limited | |
|---|---|---|---|---|---|
| | Note | **2004 $** | 2003 $ | **2004 $** | 2003 $ |
| **Revenues from ordinary activities** | 2 | **355,235** | 136,404 | **355,235** | 136,404 |
| Total expenses from ordinary activities | 2 | **(7,944,965)** | (4,113,174) | **(7,944,965)** | (4,113,174) |
| **Profit(loss) from ordinary activities before related income tax expense** | | **(7,589,730)** | (3,976,770) | **(7,589,730)** | (3,976,770) |
| Income tax expense (benefit) relating to ordinary activities | 3 | – | – | – | – |
| **Profit(loss) from ordinary activities after related income tax expense** | | **(7,589,730)** | (3,976,770) | **(7,589,730)** | (3,976,770) |
| Net profit(loss) | | **(7,589,730)** | (3,976,770) | **(7,589,730)** | (3,976,770) |
| **Net profit(loss) attributable to members of EpiTan Limited** | | **(7,589,730)** | (3,976,770) | **(7,589,730)** | (3,976,770) |
| Total changes in equity other than those resulting from transactions with owners as owners | | **(7,589,730)** | (3,976,770) | **(7,589,730)** | (3,976,770) |
| Basic earnings per share - cents per share | 15 | **(6.9)** | (4.6) | – | – |

# statement of financial position

The accompanying notes form part of these financial statements

| | | Consolidated | | EpiTan Limited | |
|---|---|---|---|---|---|
| | Note | **2004 $** | 2003 $ | **2004 $** | 2003 $ |
| **Current assets** | | | | | |
| Cash assets | 16(a) | 5,480,367 | 2,611,853 | 5,480,367 | 2,611,859 |
| Receivables | 4 | 78,349 | 30,832 | 78,349 | 30,832 |
| Other | 5 | 123,604 | 105,643 | 123,604 | 105,643 |
| **Total current assets** | | **5,682,320** | **2,748,328** | **5,682,320** | **2,748,334** |
| **Non current assets** | | | | | |
| Receivables | 4 | – | – | 4,362,805 | 5,110,098 |
| Property, plant and equipment | 6 | 119,805 | 147,176 | 119,805 | 147,176 |
| Intangible assets | 7 | 4,444,818 | 5,170,662 | 82,014 | 60,560 |
| Other financial assets | 8 | – | – | 170 | 169 |
| **Total non current assets** | | **4,564,623** | **5,317,838** | **4,564,794** | **5,318,003** |
| **Total assets** | | **10,246,943** | **8,066,166** | **10,247,114** | **8,066,337** |
| **Current liabilities** | | | | | |
| Payables | 10 | 1,282,558 | 465,826 | 1,282,558 | 465,826 |
| Provisions | 11 | 87,781 | 69,625 | 87,781 | 69,625 |
| **Total current liabilities** | | **1,370,339** | **535,451** | **1,370,339** | **535,451** |
| **Non current liabilities** | | | | | |
| Provisions | 11 | 22,103 | – | 22,103 | – |
| **Total non current liabilities** | | **22,103** | **–** | **22,103** | **–** |
| **Total liabilities** | | **1,392,442** | **535,451** | **1,392,442** | **535,451** |
| **Net assets** | | **8,854,501** | **7,530,715** | **8,854,672** | **7,530,886** |
| **Equity** | | | | | |
| Contributed equity | 12 | 25,493,957 | 16,580,441 | 25,493,957 | 16,580,441 |
| Accumulated losses | 13 | (16,639,456) | (9,049,726) | (16,639,285) | (9,049,555) |
| **Total equity** | | **8,854,501** | **7,530,715** | **8,854,672** | **7,530,886** |

# statement of cash flows

| | Note | Consolidated 2004 $ | Consolidated 2003 $ | EpiTan Limited 2004 $ | EpiTan Limited 2003 $ |
|---|---|---|---|---|---|
| **Cash flows from operating activities** | | | | | |
| Refund from ATO | | **285,351** | 140,428 | **285,351** | 140,428 |
| Payments to suppliers and employees | | **(6,632,032)** | (3,334,729) | **(6,501,164)** | (3,248,946) |
| Interest received | | **344,180** | 152,992 | **344,180** | 152,992 |
| Net cash provided by (used in) operating activities | 16(b) | **(6,002,501)** | (3,041,309) | **(5,871,633)** | (2,955,526) |
| **Cash flows from investing activities** | | | | | |
| Payments for property, plant and equipment | | **(15,254)** | (48,727) | **(15,254)** | (48,727) |
| Loans to related parties | | **–** | – | **(130,874)** | (85,769) |
| Payments for trademarks | | **(20,714)** | (17,012) | **(20,714)** | (17,012) |
| Payments for patents | | **(6,533)** | (9,087) | **(6,533)** | (9,087) |
| Net cash provided by (used in) investing activities | | **(42,501)** | (74,826) | **(173,375)** | (160,595) |
| **Cash flows from financing activities** | | | | | |
| Proceeds from issue of ordinary shares | | **9,793,772** | 1,197,950 | **9,793,772** | 1,197,950 |
| Proceeds from ordinary shares not yet issued | | **–** | 118,429 | – | 118,429 |
| Payment of share issue costs | | **(880,256)** | (2,491) | **(880,256)** | (2,491) |
| Net cash provided by (used in) financing activities | | **8,913,516** | 1,313,888 | **8,913,516** | 1,313,888 |
| Net increase/(decrease) in cash held | | **2,868,514** | (1,802,247) | **2,868,508** | (1,802,233) |
| Cash at beginning of the year | | **2,611,853** | 4,414,100 | **2,611,859** | 4,414,092 |
| Cash at end of the year | 16(a) | **5,480,367** | 2,611,853 | **5,480,367** | 2,611,859 |

# notes to and forming part of the financial statements

## 1 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The financial report is a general purpose financial report that has been prepared in accordance with Accounting Standards, Urgent Issues Group Consensus Views, other authoritative pronouncements of the Australian Accountancy Standards Board and the Corporations Act 2001. The financial report has been prepared on an accruals basis and is based on historical costs and does not take into account changing money values or, except where stated, current valuations of non current assets. Cost is based on the fair values of the consideration given in exchange for assets. The accounting policies have been consistently applied, unless otherwise stated.

The following is a summary of the significant accounting policies adopted by the economic entity in the preparation of the financial report.

### (a) Principles of consolidation

The consolidated accounts comprise the accounts of EpiTan Limited and its controlled entities. A controlled entity is any entity controlled by EpiTan Limited. Control exists where EpiTan Limited has the capacity to dominate the decision-making in relation to the financial and operating activities of another entity so that the other entity operates with EpiTan Limited to achieve the objectives of EpiTan Limited. A list of controlled entities is contained in Note 9 to the financial statements.

All inter-company balances and transactions between entities in the economic entity, including any unrealised profits or losses, have been eliminated on consolidation.

Where controlled entities have entered or left the economic entity during the year, their operating results have been included from the date control was obtained or until the date control ceased.

### (b) Income tax

The consolidated entity adopts the liability method of tax effect accounting whereby the income tax expense is based on the profit from ordinary activities adjusted for any permanent differences.

Timing differences which arise due to the different accounting periods in which items of revenue and expense are included in the determination of accounting profit and taxable income are brought to account as either a provision for deferred income tax or as a future income tax benefit at the rate of income tax applicable to the period in which the benefit will be received or the liability will become payable.

Future income tax benefits are not brought to account unless realisation of the asset is assured beyond any reasonable doubt. Future income tax benefits in relation to tax losses are not brought to account unless there is virtual certainty of realisation of the benefit.

The amount of benefits brought to account or which may be realised in the future is based on the assumption that no adverse change will occur in income tax legislation and the anticipation that the company will derive sufficient future assessable income and comply with the conditions of deductibility imposed by the law.

### (c) Cash

For the purpose of the statement of cash flows, cash includes cash on hand and at call deposits with banks or financial institutions, bank bills and negotiable financial instruments.

### (d) Property, plant and equipment

Property, plant and equipment are brought to account at cost or at independent or directors' valuation, less, where applicable, any accumulated depreciation or amortisation. The carrying amount of property, plant and equipment is reviewed annually by directors to ensure it is not in excess of the recoverable amount from these assets. The recoverable amount is assessed on the basis of the expected net cash flows which will be received from the assets' employment and subsequent disposal. The expected net cash flows have not been discounted to their present values in determining recoverable amounts.

The depreciable amount of all fixed assets is depreciated over the assets' useful lives to the economic entity commencing from the time the asset is held ready for use.

The depreciation rates used for each class of depreciable assets are:

| Class of fixed asset | Depreciation rate |
|---|---|
| Office equipment | 20 – 40% |
| Furniture and fittings | 20% |

**1 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES** CONTINUED

(e) **Investments**

Non-current investments are brought to account at cost or at directors' valuation. The carrying amount of investments is reviewed annually by directors to ensure it is not in excess of the recoverable amount of these investments. The recoverable amount is assessed from the underlying net assets in the particular entities. The expected net cash flows from investments have not been discounted to their present value in determining the recoverable amounts.

(f) **Research and development expenditure**

Research and development costs are charged to profit from ordinary activities before income tax as incurred or deferred where it is expected beyond any reasonable doubt that sufficient future benefits will be derived so as to recover those deferred costs. No research and development costs have been deferred during this financial year.

Deferred research and development expenditure is amortised on a straight line basis over the period during which the related benefits are expected to be realised, once commercial production has commenced.

(g) **Intellectual property**

*(i) Sub-licence*

The sub-licence to develop and commercialise Melanotan has been recorded at cost. Cost is based on the fair value of the consideration given in exchange for the assets.

The consideration given for the acquisition of the sub-licence was the issue of 11,167,000 ordinary shares and attaching options in the company. Hence the cost of the sub-licence has been determined by assessing the fair value of net assets of the economic entity immediately after the sub-licence was acquired. For the purpose of valuing the assets of the company, an independent valuation of the sub-licence was performed. The valuation was based on discounted future cash flows expected to flow from the right to the sub-licence. The valuation was adjusted for the probability of success.

The directors have determined that it is appropriate to record the sub-licence at cost rather than revalued to market value at this time.

*(ii) Amortisation of Sub-licence*

The sub-licence to develop and commercialise Melanotan is amortised on a straight-line basis over 10 years. The directors have assessed this to be the period over which the future economic benefits of the sub-licence are expected to be realised. The period approximates the remaining life and likely extensions of the patents subject to the sub-licence.

*(iii) Amortisation of Trademarks*

Trademarks are amortised on a straight line basis over their expected useful lives.

(h) **Payables**

Liabilities are recognised for amounts to be paid in the future for goods and services received, whether or not billed to the economic entity.

(i) **Employee benefits**

Provision is made for the economic entity's liability for employee benefits arising from services rendered by employees to balance date. Liabilities arising in respect of salaries and wages, annual leave and any other employee benefits expected to be settled within twelve months of the reporting date are measured at their nominal amount based on remuration rates which are expected to be paid when the liability is settled. All other employee benefit liabilities are measured at the present value future cash outflow to be made.

Employee benefits 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 benefits are charged against profits on a net basis in their respective categories.

The value of the employee option scheme described in note 22 is not being charged as an employee benefit expense.

Contributions are made by the economic entity to employee superannuation funds and are charged as expenses when incurred.

## 1 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES CONTINUED

### (j) Directors' remuneration

Directors' remuneration includes all remuneration in connection with the management of the company and means any money, consideration or benefit. Remuneration includes the value of share options granted. Options over shares have been valued at grant date using an option pricing model in accordance with current ASIC guidance, Australian Exposure Draft ED 108 and International Exposure Draft ED 2. The value of options issued to directors has been included in the determination of directors' remuneration during the period from grant date to vesting date. In accordance with Australian Accounting Standards, share options have not been expensed.

### (k) Revenue

Interest revenue is recognised on a proportional basis.

### (l) Share capital

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

Any transaction costs arising on the issue of ordinary shares are recognised directly in equity as a reduction of the shares proceeds received.

### (m) Earnings per share

*(i) Basic earnings per share*

Basic earnings per share is determined by dividing net profit after income tax attributable to members of the company, excluding any costs of servicing equity other than ordinary shares, by the weighted average number of ordinary shares outstanding during the financial year, adjusted for bonus elements in ordinary shares issued during the year.

*(ii) Diluted earnings per share*

Diluted earnings per share adjusts the figures used in the determination of basic earnings per share to take into account the after income tax effect of interest and other financing costs associated with dilutive potential ordinary shares and the weighted average number of shares assumed to have been issued for no consideration in relation to dilutive potential ordinary shares.

### (n) Goods and Services Tax (GST)

Revenues, expenses and assets are recognised net of the amount of GST, except where the amount of GST incurred is not recoverable from the Australian Tax Office. In these circumstances the GST is recognised as part of the cost of acquisition of the asset or as part of an item of the expense receivables and payables in the statement of financial position are shown inclusive of GST.

### (o) Leases

Leases payments for operating leases, where substantially all the risks and benefits remain with the lessors, are charged as expenses in the periods in which they are incurred.

### (p) Comparatives

Where necessary, comparatives have been reclassified and repositioned for consistency with current year disclosure.

### (q) Contributed equity

Issued and paid up capital is recognised at the fair value of consideration received by the company. Any transaction costs arising on the issue of ordinary shares are recognised directly in equity as a reduction of the share proceeds received.

## notes to and forming part of the financial statements continued

| | | Consolidated | | EpiTan Limited | |
|---|---|---|---|---|---|
| | Note | **2004 $** | 2003 $ | **2004 $** | 2003 $ |
| **2** | **PROFIT/(LOSS) FROM ORDINARY ACTIVITIES** | | | | |
| (a) | **Revenues from ordinary activities** | | | | |
| | Interest revenue – other persons | **355,235** | 136,404 | **355,235** | 136,404 |
| | **Total revenues** | **355,235** | 136,404 | **355,235** | 136,404 |
| **(b)** | **Expenses from ordinary activities** | | | | |
| | Clinical development costs | **2,485,534** | 1,693,328 | **1,738,236** | 946,030 |
| | Drug delivery research costs | **3,053,105** | 949,439 | **3,053,105** | 949,439 |
| | Occupancy costs | **86,184** | 75,080 | **86,184** | 75,080 |
| | Pharmaceutical marketing development | **–** | – | **–** | – |
| | Marketing costs | **640,549** | 118,275 | **640,549** | 118,275 |
| | Finance & administration costs | **1,679,593** | 1,277,052 | **2,426,891** | 2,024,350 |
| | Total expenses from ordinary activities | **7,944,965** | 4,113,174 | **7,944,965** | 4,113,174 |
| (c) | **Profit/(loss) from ordinary activities before income tax has been determined after:** | | | | |
| | Depreciation | **37,200** | 43,086 | **37,200** | 43,086 |
| | Amortisation of sub-licence | **747,298** | 747,298 | **–** | – |
| | Amortisation of trademarks | **5,793** | 3,873 | **5,793** | 3,873 |
| | Research & development costs | **4,791,341** | 1,895,496 | **4,791,341** | 1,895,496 |
| | Doubtful debts – wholly owned subsidiary | **–** | – | **878,166** | 833,082 |
| | Loss on sale of property, plant and equipment | **4,862** | – | **4,862** | – |
| | Operating lease expense – minimum lease payments | **131,327** | 83,964 | **131,327** | 83,964 |
| **3** | **INCOME TAX EXPENSE** | | | | |
| (a) | The prima facie tax on profit(loss) from ordinary activities before income tax is reconciled to the income tax expense(benefit) as follows: | | | | |
| | Prima facie tax payable on profit(loss) from ordinary activities before income tax at 30% | **(2,276,919)** | (1,193,031) | **(2,276,919)** | (1,193,031) |
| | Add: | | | | |
| | Tax effect of permanent differences | | | | |
| | – non deductible amortisation | **1,738** | 1,162 | **1,738** | 1,162 |
| | – non deductable legal fees | **13,560** | – | **13,560** | – |
| | – research and development deduction | **(359,351)** | – | **(359,351)** | – |
| | Write off FITB due to lack of virtual certainty | **2,620,972** | 1,191,869 | **2,620,972** | 1,191,869 |
| | | – | – | – | – |
| (b) | Future income tax benefits arising from unconfirmed tax losses and net timing differences not brought to account at balance date as realisation of the benefit is not regarded as virtually certain. The benefits will only be obtained if the conditions set out in note 1(b) occur: | | | | |
| | Tax losses | **4,292,966** | 2,086,038 | **3,685,978** | 1,928,464 |
| | Net timing differences | **718,910** | 618,975 | **889,890** | 776,620 |
| | | **5,011,876** | 2,705,013 | **4,575,868** | 2,705,104 |

| | | Consolidated | | EpiTan Limited | |
|---|---|---|---|---|---|
| | Note | **2004 $** | 2003 $ | **2004 $** | 2003 $ |
| **4 RECEIVABLES** | | | | | |
| **Current** | | | | | |
| Sundry debtors | | **67,294** | 30,832 | **67,294** | 30,832 |
| Accrued income | | **11,055** | – | **11,055** | – |
| | | **78,349** | 30,832 | **78,349** | 30,832 |
| **Non-Current** | | | | | |
| Receivable from wholly owned entity | 20 | **–** | – | **7,740,678** | 7,609,805 |
| Provision for non-recovery | | **–** | – | **(3,377,873)** | (2,499,707) |
| | | **–** | – | **4,362,805** | 5,110,098 |
| **5 OTHER ASSETS** | | | | | |
| **Current** | | | | | |
| Prepayments | | **123,604** | 105,643 | **123,604** | 105,643 |
| **6 PROPERTY, PLANT AND EQUIPMENT** | | | | | |
| Office equipment | | | | | |
| At cost | | **183,828** | 192,483 | **183,828** | 192,483 |
| Less: Accumulated depreciation | | **(113,976)** | (95,163) | **(113,976)** | (95,163) |
| | | **69,852** | 97,320 | **69,852** | 97,320 |
| Furniture and fittings | | | | | |
| At cost | | **87,838** | 77,358 | **87,838** | 77,358 |
| Less: Accumulated depreciation | | **(37,885)** | (27,502) | **(37,885)** | (27,502) |
| | | **49,953** | 49,856 | **49,953** | 49,856 |
| Total property, plant and equipment | | **119,805** | 147,176 | **119,805** | 147,176 |

**Movements in carrying amounts**
Movements in the carrying amounts for each class of property, plant and equipment between the beginning and the end of the financial year

| | Office equipment $ | Furniture and fittings $ | Total $ |
|---|---|---|---|
| Consolidated & EpiTan Limited - 2004 | | | |
| Carrying amount at the beginning of year | 97,320 | 49,856 | 147,176 |
| Additions | 4,774 | 10,480 | 15,254 |
| Disposals | (13,430) | – | (13,430) |
| Depreciation written back on disposal | 8,005 | – | 8,005 |
| Depreciation expense | (26,817) | (10,383) | (37,200) |
| Carrying amount at the end of year | 69,852 | 49,953 | 119,805 |

## notes to and forming part of the financial statements continued

| | | Note | Consolidated 2004 $ | Consolidated 2003 $ | EpiTan Limited 2004 $ | EpiTan Limited 2003 $ |
|---|---|---|---|---|---|---|
| **7** | **INTANGIBLE ASSETS** | | | | | |
| | Sub-licence to develop and commercialise Melanotan – at cost | | **7,472,983** | 7,472,983 | **–** | – |
| | Less: Accumulated amortisation | | **(3,110,179)** | (2,362,881) | **–** | – |
| | | | **4,362,804** | 5,110,102 | **–** | – |
| | Trademarks at cost | | **68,281** | 47,567 | **68,281** | 47,567 |
| | Less: Accumulated amortisation | | **(9,985)** | (4,192) | **(9,985)** | (4,192) |
| | | | **58,296** | 43,375 | **58,296** | 43,375 |
| | Patents at cost | | **23,718** | 17,185 | **23,718** | 17,185 |
| | | | **4,444,818** | 5,170,662 | **82,014** | 60,560 |
| **8** | **OTHER FINANCIAL ASSETS** | | | | | |
| | **Non-Current** | | | | | |
| | Investments at cost comprise: | | | | | |
| | Shares in unlisted controlled entities | 9 | **–** | – | **170** | 169 |
| **9** | **INTERESTS IN SUBSIDIARIES** | | | | | |
| | Melanotan (Australia) Pty Ltd Incorporated in Australia. Percentage of equity interest held by the consolidated entity: 100% (2003: 100%) | | | | | |
| | EpiTan Pharmaceuticals Pty Ltd. Incorporated in Australia. Percentage of equity interest held by the consolidated entity 100% (2003: 0%) | | | | | |
| **10** | **PAYABLES** | | | | | |
| | Current | | | | | |
| | Trade creditors | | **1,179,726** | 235,929 | **1,179,726** | 235,929 |
| | Sundry creditors and accrued expenses | | **102,832** | 111,468 | **102,832** | 111,468 |
| | Ordinary shares yet to be issued | | **–** | 118,429 | **–** | 118,429 |
| | | | **1,282,558** | 465,826 | **1,282,558** | 465,826 |
| (a) | Aggregate amounts payable to: | | | | | |
| | – directors and director-related entities | | **46,610** | 47,401 | **46,610** | 47,401 |
| (b) | Australian dollar equivalents of amounts payable in foreign currencies not effectively hedged: | | | | | |
| | – Swedish krone | | **–** | 14,423 | **–** | 14,423 |
| | – US dollars | | **596,048** | 96,991 | **596,048** | 96,991 |
| | – Euro | | **83,846** | – | **83,846** | – |
| | – British Pounds | | **77,120** | – | **77,120** | – |
| (c) | Terms and conditions: Trade and sundry creditors are non-interest bearing and normally settled on 30 day terms. | | | | | |

| | | Consolidated | | EpiTan Limited | |
|---|---|---|---|---|---|
| | Note | **2004 $** | 2003 $ | **2004 $** | 2003 $ |
| **11 PROVISIONS** | | | | | |
| **Current** | | | | | |
| Employee benefits | | **87,781** | 69,625 | **87,781** | 69,625 |
| **Non Current** | | | | | |
| Employee Benefits | | **22,103** | – | **22,103** | – |
| **12 CONTRIBUTED EQUITY** | | | | | |
| (a) Issued and paid up capital fully paid ordinary shares | | **25,493,957** | 16,580,441 | 25,493,957 | 16,580,441 |
| 114,449,085 fully paid ordinary shares (2003: 91,439,832) | | | | | |

| | No. | **2004 $** | No. | 2003 $ |
|---|---|---|---|---|
| (b) Movements in shares on issue | | | | |
| At the beginning of the financial year | 91,439,832 | **16,580,441** | 86,414,254 | 15,382,490 |
| Issued during the year | | | | |
| – options exercised | 8,509,253 | **2,398,772** | 5,025,578 | 1,197,951 |
| – placement | 14,500,000 | **7,395,000** | – | – |
| Less: transaction costs | – | **(880,256)** | – | – |
| | – | | – | – |
| | 114,449,085 | 25,493,957 | 91,439,832 | 16,580,441 |

(c) Share Options

As at 30 June 2004 the following share options existed which if exercised, would result in the issue of fully paid ordinary shares.

| Expiry Date | Exercise price | Number of options |
|---|---|---|
| 30 September 2005 | $0.30 / share | 141,556 |
| 31 March 2006 | $0.30 / share | 750,000 |
| 3 April 2006 | $0.10 / share | 750,000 |
| 22 October 2006 | $0.10 / share | 1,300,000 |
| 31 December 2007 | $0.74 / share | 750,000 |
| 1 January 2008 | $0.66 / share | 375,000 |
| 2 February 2008 | $0.16 / share | 750,000 |
| 13 June 2008 | $0.29 / share | 500,000 |
| 18 April 2009 | $0.87 / share | 300,000 |

During the year the following share options were issued which if exercised, would result in the issue of fully paid ordinary shares.

| Expiry Date | Exercise price | Number of options |
|---|---|---|
| 31 December 2007 | $0.74 / share | 750,000 |
| 1 January 2008 | $0.66 / share | 375,000 |
| 13 June 2008 | $0.29 / share | 500,000 |
| 18 April 2009 | $0.87 / share | 300,000 |

(d) Terms and conditions of contributed 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.

## notes to and forming part of the financial statements continued

| | | Consolidated | | EpiTan Limited | |
|---|---|---|---|---|---|
| | Note | **2004 $** | 2003 $ | **2004 $** | 2003 $ |
| **13 ACCUMULATED LOSSES** | | | | | |
| Accumulated losses at the beginning of the year | | **(9,049,726)** | (5,072,956) | **(9,049,555)** | (5,072,785) |
| Net loss attributable to the members of EpiTan Limited | | **(7,589,730)** | (3,976,770) | **(7,589,730)** | (3,976,770) |
| Accumulated losses at the end of the financial year | | **(16,639,456)** | (9,049,726) | **(16,639,285)** | (9,049,555) |
| **14 LEASE COMMITMENTS** | | | | | |
| **Operating lease commitments** Non-cancellable operating leases Contracted for but not capitalised in the accounts: | | | | | |
| Payable | | | | | |
| – not later than 1 year | | **117,578** | 90,354 | **117,578** | 90,354 |
| – later than 1 year but not later than 5 years | | **67,297** | 150,590 | **67,297** | 150,590 |
| | | **184,875** | 240,944 | **184,875** | 240,944 |

**15 EARNINGS PER SHARE (EPS)**

| | | Consolidated | |
|---|---|---|---|
| | | **2004** | 2003 |
| (a) | Basic earnings per share – cents per share | **(6.9)** | (4.6) |
| (b) | The Weighted Average Number of Ordinary Shares (WANOS) used in the calculation of basic earnings per share | **109,469,542** | 86,923,303 |
| (c) | The numerator used in the calculation of basic earnings per share. | **(7,589,730)** | (3,976,770) |

(d) Potential Ordinary Shares not considered Dilutive

As at 30 June 2004 the company had on issue 5,616,556 unlisted options over unissued capital. The details of which are included in Notes 12(c) and 22(b). These options are not considered dilutive as they do not increase the net loss per share.

| | | Consolidated | | EpiTan Limited | |
|---|---|---|---|---|---|
| | Note | **2004 $** | 2003 $ | **2004 $** | 2003 $ |
| **16** | **CASH FLOW INFORMATION** | | | | |
| (a) | Reconciliation of Cash For the purposes of the Statement of Cash Flows, cash includes cash on hand and with banks and in investments in money market instruments | | | | |
| | Cash at the end of the financial year as shown in the Statement of Cash Flows is reconciled to the related items in the balance sheet as follows: | | | | |
| | Cash at bank | **168,028** | 1,134,008 | **168,028** | 1,134,014 |
| | Cash on hand | **3,018** | 31 | **3,018** | 31 |
| | Bank bills & income security notes | **3,994,000** | – | **3,994,000** | – |
| | Deposits on call | **1,315,321** | 1,477,814 | **1,315,321** | 1,477,814 |
| | | **5,480,367** | 2,611,853 | **5,480,367** | 2,611,859 |
| (b) | Reconciliation of cash flows from operating activities with operating profit(loss) | | | | |
| | Operating profit(loss) after income tax | **(7,589,730)** | (3,976,770) | **(7,589,730)** | (3,976,770) |
| | Non cash flows in operating (loss): | | | | |
| | Depreciation expense | **37,200** | 43,086 | **37,200** | 43,086 |
| | Amortisation expense | **753,091** | 751,171 | **5,793** | 3,873 |
| | Doubtful debt expense | **–** | – | **878,166** | 833,082 |
| | Loss of sales on non-current assets | **4,862** | – | **4,862** | – |
| | Changes in assets and liabilities: | | | | |
| | (Increase)/decrease in receivables | **(47,517)** | (1,230) | **(47,517)** | (1,230) |
| | (Increase)/decrease in prepayments | **(17,961)** | (66,252) | **(17,961)** | (66,252) |
| | Increase/(decrease) in payables | **817,295** | 193,015 | **817,295** | 193,014 |
| | Increase/(decrease) in provisions | **40,259** | 15,671 | **40,259** | 15,671 |
| | Net cash used in operating activities | **(6,002,501)** | (3,041,309) | **(5,871,633)** | (2,955,526) |

## 17. DIRECTORS AND EXECUTIVES' DISCLOSURES

As required by AASB 1046 details of directors and specified executives remuneration is detailed below.

**The specified directors of EpiTan Limited during the year were:**

W.A. Millen
H.P.K. Agersborg
T.E. Winters
S.R. McLiesh

**The specified executives of EpiTan Limited during the year were:**

I.M. Kirkwood (Chief Financial Officer and Company Secretary)

EpiTan Limited has no other specified executives.

## notes to and forming part of the financial statements continued

### REMUNERATION OF DIRECTORS

| Specified directors | Primary salaries & fees | Bonus | Non-monetary benefits | Post employment Super | Post employment Other | Equity options | Total |
|---|---|---|---|---|---|---|---|
| W.A. Millen | 229,611 | 50,000 | 12,446 | 25,390 | – | – | 317,447 |
| H.P.K. Agersborg | 36,666 | – | – | – | – | 33,638 | 70,304 |
| T.E. Winters | 36,666 | – | – | – | – | 33,638 | 70,304 |
| S.R. McLiesh | 37,982 | – | – | 3,562 | – | 62,762 | 104,306 |
| Total | 340,925 | 50,000 | 12,446 | 28,952 | 0 | 130,038 | 562,361 |

### REMUNERATION OF EXECUTIVES

| Specified executives | Primary salaries & fees | Bonus | Non-monetary benefits | Post employment Super | Post employment Other | Equity options | Total |
|---|---|---|---|---|---|---|---|
| I.M. Kirkwood | 97,546 | 5,000 | – | 14,229 | – | 50,887 | 167,662 |

(a) Mr I. Kirkwood is Chief Financial Officer and Company Secretary. Mr Kirkwood was granted options as part of a remuneraton review in January 2004.

(b) Remuneration policy

The Remuneration and Nomination Committee of the Board of directors of Epitan Limited assesses the appropriateness of the nature and amount of remuneration of directors and officers at least annually by reference to relevant employment market conditions and by the engagement of a specialist remuneration consultant with experience in the healthcare and biotechnology industries. The overall objective is to ensure the engagement and retention of the highest quality board and executive team for the benefit of all stakeholders.

The committee, assisted by the external consultant, seeks to link the nature and amount of compensation to the company's financial and operational performance. All directors and executives are eligible to participate in the company's Option Plan. In addition, executives may be entitled to annual bonuses payable at the discretion of the Committee for specific performance achievements which have demonstratably contributed to an increase in shareholder value.

The Committee has determined that an employment agreement be entered into with the Chief Executive Officer and with no other executives. The current employment agreement with the CEO commenced on the 1st February 2000 and continues for 5 years. The agreement has a 6 month notice period and provides for payment of an amount in lieu of notice for that period.

### REMUNERATION OPTIONS: GRANTED AND VESTED DURING THE YEAR

| Specified directors | Vested number | Granted number | Grant date | Value per option at grant date | Exercise price per share | First exercise date | Last exercise date |
|---|---|---|---|---|---|---|---|
| W.A. Millen | – | – | – | – | – | – | – |
| H.P.K. Agersborg | 750,000 | 250,000 | 10 Nov 2003 | 0.51 | 0.735 | 10 Nov 2004 | 31 Dec 2007 |
| T.E. Winters | 750,000 | 250,000 | 10 Nov 2003 | 0.51 | 0.735 | 10 Nov 2004 | 31 Dec 2007 |
| S.R. McLiesh | 187,500 | 250,000 | 10 Nov 2003 | 0.51 | 0.735 | 10 Nov 2004 | 31 Dec 2007 |
| **Specified executives** | | | | | | | |
| I.M. Kirkwood | 250,000 | 125,000 | 1 Jan 2004 | 0.44 | 0.655 | 1 Jan 2006 | 1 Jan 2008 |

### SHARES ISSUED ON EXERCISE OF REMUNERATION OPTIONS

| Specified directors | Shares issued number | Paid $ per share |
|---|---|---|
| H.P.K. Agersborg | 750,000 | 0.30 |
| T.E. Winters | 750,000 | 0.30 |

| | Note | Consolidated 2004 $ | Consolidated 2003 $ | EpiTan Limited 2004 $ | EpiTan Limited 2003 $ |
|---|---|---|---|---|---|
| **18 AUDITORS' REMUNERATION** | | | | | |
| Amounts received or due and receivable by William Buck for: | | | | | |
| – audit services and review | | **24,040** | 20,000 | **24,040** | 20,000 |
| – other services | | **13,691** | 29,642 | **13,691** | 29,642 |
| | | **37,731** | 49,642 | **37,731** | 49,642 |

**19 RELATED PARTY DISCLOSURES**

**Directors**

The directors of EpiTan Limited during the financial year were:

W. A. Millen
H. P. K. Agersborg
T. E. Winters
S.R. McLiesh

**Wholly-owned group transactions**

*Loans*

The loan receivable by EpiTan Limited from Melanotan (Australia) Pty Ltd is non-interest bearing. Repayment of the loan will commence upon commercialisation of the company's drug candidate. A provision for non-recovery has been raised in the accounts of EpiTan Limited to the extent that a deficiency in net assets exists in Melanotan (Australia) Pty Ltd.

**Equity instruments of directors**

*Interests at balance date*

Interests in equity instruments of EpiTan Limited held by directors of the reporting entity and their director-related entities:

| | Ordinary shares fully paid 2004 Number | Ordinary shares fully paid 2003 Number | Options over ordinary shares 2004 Number | Options over ordinary shares 2003 Number |
|---|---|---|---|---|
| W. A. Millen | **17,726,375** | 19,706,144 | **–** | – |
| H.P.K. Agersborg | **750,000** | – | **250,000** | 750,000 |
| T. E. Winters | **16,065,415** | 15,315,415 | **250,000** | 750,000 |
| S.R. McLiesh | **–** | – | **1,000,000** | 750,000 |

During the year HPK Agersborg and TE Winters each converted 750,000 options into ordinary shares. At the 2003 AGM shareholders agreed to issue 250,000 options to each non-executive director.

All equity dealings with directors have been entered into with terms and conditions no more favourable than those that the entity would have adopted if dealing at arm's length.

**20 SEGMENT INFORMATION**

The economic entity operates solely in the biotechnology industry. The economic entity operates predominantly in Australia.

## 21 FINANCIAL INSTRUMENTS

(a) Interest rate risk

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

| | Weighted Average Effective Interest Rate | | Non-Interest Bearing | | Balances Subject to a Floating Interest Rate | | Total | |
|---|---|---|---|---|---|---|---|---|
| | **2004** % | 2003 % | **2004** $ | 2003 $ | **2004** $ | 2003 $ | **2004** $ | 2003 $ |
| *(i) Financial Assets* | | | | | | | | |
| Cash at bank, deposits and income securities | **5.8** | 4.1 | **171,046** | 31 | **5,309,322** | 2,611,822 | **5,480,367** | 2,611,853 |
| Receivables | **N/A** | N/A | **78,349** | 30,832 | – | – | 78,349 | 30,832 |
| Total | | | **249,395** | 30,863 | **5,309,322** | 2,611,822 | **5,80,367** | 2,642,685 |
| *(ii) Financial Liabilities* | | | | | | | | |
| Payables | **N/A** | N/A | **1,282,558** | 465,826 | – | – | **1,282,558** | 465,826 |
| Total | | | **1,282,558** | 465,826 | – | – | **1,282,558** | 465,826 |

(b) Net fair values

All financial assets and liabilities have been recognised at the balance date at their net fair values.

(c) Credit risk exposures

The economic entity's maximum exposure to credit risk at balance date in relation to each class of recognised financial assets is the carrying amount of those assets as indicated in the statement of financial position.

## 22 EMPLOYEE BENEFITS

| | Consolidated | | EpiTan Limited | |
|---|---|---|---|---|
| | **2004** $ | 2003 $ | **2004** $ | 2003 $ |
| (a) The aggregate employee benefit liability is comprised of : | | | | |
| – Provisions | **109,884** | 69,625 | **109,884** | 69,625 |
| – Accrued wages, salaries and on costs | **12,526** | 78,168 | **12,526** | 78,168 |
| | **122,410** | 147,793 | **122,410** | 147,793 |

(b) Employee option plan

An employee option plan has been established where directors, staff and consultants are issued with options over the ordinary shares of EpiTan Limited. The options, issued for nil consideration, are issued in accordance with performance guidelines established by the directors of EpiTan Limited. The options are issued for a term of 5 years, however this does vary for the various plan participants. The options cannot be transferred and will not be quoted on the ASX. There are currently three directors, five staff and three consultants eligible for this scheme.

Information with respect to the number of options granted under the employee option scheme is as follows :

| | **2004** | | 2003 | |
|---|---|---|---|---|
| | **Number of Options** | **Weighted average exercise price** | Number of Options | Weighted average exercise price |
| Balance at beginning of year | **6,714,895** | **$0.20** | 5,385,937 | $0.20 |
| – granted | **1,925,000** | **$0.63** | 1,650,000 | $0.22 |
| – forfeited | **–** | **–** | (321,042) | $0.30 |
| – exercised | **(3,023,339)** | **$0.25** | – | – |
| Balance at end of year | **5,616,556** | **$0.32** | 6,714,895 | $0.20 |
| Exercisable at end of year | **2,487,500** | **$0.17** | 3,200,277 | $0.19 |

**EMPLOYEE BENEFITS** (CON'T)

The following table summarises information about options outstanding and exercisable at 30 June 2004.

| Exercise price | Expiry date | Number of options: Outstanding | Exercisable |
|---|---|---|---|
| $0.30 | 30 September 2005 | 141,556 | |
| $0.30 | 31 March 2006 | 750,000 | 187,500 |
| $0.10 | 3 April 2006 | 750,000 | 750,000 |
| $0.10 | 22 October 2006 | 1,300,000 | 1,300,000 |
| $0.74 | 31 December 2007 | 750,000 | – |
| $0.66 | 1 January 2008 | 375,000 | – |
| $0.16 | 2 February 2008 | 750,000 | 250,000 |
| $0.29 | 13 June 2008 | 500,000 | – |
| $0.87 | 18 April 2009 | 300,000 | – |
| | | 5,616,556 | 2,487,500 |

## 23 SUBSEQUENT EVENTS

– Capital raising
On 11 August 2004 EpiTan Limited issued 10,500,000 ordinary shares at $0.76 each to two European fund managers raising $7,980,000 before costs.

At the same time EpiTan issued to the same two institutions 6,667,362 options exercisable at $1.03 each at any time over the next three years (ending date being 11 August 2007). The options were issued for nil consideration

– Acquired two prescription dermatology products, Linotar and Exorex from TransDermal Pharmaceuticals Pty Ltd in July

– Entered into an agreement to in-license Zindaclin from UK based Strakan International Limited in July.

## 24 IMPACT OF ADOPTING AASB EQUIVALENTS TO IASB STANDARDS

EpiTan Limited has reviewed its accounting policies and financial reporting in light of the transition from current Australian Standards to Australia Equivalents of International Financial Reporting Standards (IFRS). Set out below are the key areas where accounting policies will change and may have an impact on the financial report of EpiTan Limited. At this stage the company has not been able to reliably quantify the impacts on the financial report.

Impairment of assets
Under the Australian equivalent of IAS 36 Impairment of Assets the recoverable amount of an asset is determined as the higher of the net selling price and its value in use. This will result in a change in the entity's accounting policy which determines the recoverable amount of an asset will be recognised sooner and that the amount of write downs will be greater. Reliable estimation of the future financial effects of this change in accounting policy is impractical because the conditions under which impairment will be assessed are not yet known.

Intangible assets
Under the Australian equivalent to IAS 38 Intangible Assets, costs incurred in the research phase of the development of an internally generated intangible must be expensed. This will result in a change in the group's current accounting policy which allows for the capitalization of costs incurred in the research phase of an internally generated intangible asset were future benefits are expected beyond reasonable doubt. Under the new policy, all research costs will be written off as incurred. As the entity has not capitalised any research costs to date, there will be to adjustment required upon adoption of this policy.

## notes to and forming part of the financial statements continued

**24 IMPACT OF ADOPTING AASB EQUIVALENTS TO IASB STANDARDS** (CON'T)

**Share based payments**
Under AASB 2 Share Based Payments, the company will be required to determine the fair value of options issued to employees as remuneration and recognise an expense in the Statement of Financial Performance. This standard is not limited to options and also extends to other forms of equity based remuneration. It applies to all share based payments issued after 7 November 2002 which have not vested as at 1 January 2005. Reliable estimation of the future financial effects of this change in accounting policy is impractical as the details of future equity based remuneration plans are not known.

**Income taxes**
Under the Australian equivalent to IAS 12 Income Taxes, the company will be required to use a balance sheet liability method which focuses on the tax effects of transactions and other events that affect amounts recognized in either the Statement of Financial Position or a tax based balance sheet. As the entity has significant tax losses at 30 June 2004, reliable estimation of the future financial effects of this change in accounting policy is impractical.

## directors' declaration

In the opinion of the directors:

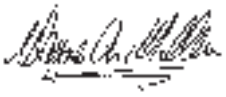
1. the financial statements and notes, of the company and of the consolidated entity, are in accordance with the Corporations Act 2001, including:

(a) giving a true and fair view of the company's and the consolidated entity's financial position as at 30 June 2004 and of their performance for the year ended on that date;

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

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

This declaration is made in accordance with a resolution of the board of directors.



**W.A. MILLEN** DIRECTOR
Dated this 17 day of August, 2004

# independent audit report

William Buck
Business Advisors
Chartered Accountants

**Independent audit report to members of**
**EpiTan Limited & controlled entities**
**ABN 88 089 644 119**

**Scope**

*The financial report and directors' responsibility*

The financial report comprises the statement of financial position, statement of financial performance, statement of cash flows, accompanying notes to the financial statements, and the directors' declaration for both EpiTan Limited (the company) and EpiTan Limited and controlled entities (the consolidated entity), for the year ended 30 June 2004. The consolidated entity comprises both the company and the entities it controlled during that year.

The directors of the company are responsible for the preparation and true and fair presentation of the financial report in accordance with the *Corporations Act 2001*. This includes responsibility for the maintenance of adequate accounting records and internal controls that are designed to prevent and detect fraud and error, and for the accounting policies and accounting estimates inherent in the financial report.

*Audit approach*

We conducted an independent audit in order to express an opinion to the members of the company. Our audit was conducted in accordance with Australian Auditing and Assurance Standards in order to provide reasonable assurance as to whether the financial report is free of material misstatement. The nature of an audit is influenced by factors such as the use of professional judgement, selective testing, the inherent limitations of internal control, and the availability of persuasive rather than conclusive evidence. Therefore, an audit cannot guarantee that all material misstatements have been detected.

We performed procedures to assess whether in all material respects the financial report presents fairly, in accordance with the *Corporations Act 2001*, Accounting Standards and other mandatory financial reporting requirements in Australia, a view which is consistent with our understanding of the company's and the consolidated entity's financial position, and of their performance as represented by the results of their operations and cash flows.

We formed our audit opinion on the basis of these procedures, which included;

- Examining, on a test basis, information to provide evidence supporting the amounts and disclosures in the financial report; and
- Assessing the appropriateness of the accounting policies and disclosures used and the reasonableness of significant accounting estimates made by the directors.

While we considered the effectiveness of management's internal controls over financial reporting when determining the nature and extent of our procedures, our audit was not designed to provide assurance on internal controls.

(1 of 2)

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## independent audit report continued

William Buck
Business Advisors
Chartered Accountants

**Independence**

In conducting our audit, we followed applicable independence requirements of Australian accounting ethical pronouncements and the *Corporations Act 2001*.

**Audit opinion**

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

(a) the Corporations Act 2001, including:

(i) gives a true and fair view of EpiTan Limited's and the consolidated entity's financial position as at 30 June 2004 and of their performance for the year ended on that date; and

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

(b) other mandatory financial reporting requirements in Australia.

William Buck
Chartered Accountants

K W Glynn
Partner

Dated this 17th day of August 2004
Melbourne, Australia.

(2 of 2)

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# additonal information required by the australian stock exchange

Additional information required by the Australian Stock Exchange and not shown elsewhere in this report is as follows. The information is current at 30 July 2004.

## 1. SHAREHOLDING

(a) Distribution of shareholders number

| Category (size of Holding) | Ordinary shares |
|---|---|
| 1 – 1,000 | 362 |
| 1,001 – 5,000 | 1,384 |
| 5,001 – 10,000 | 846 |
| 10,001 – 100,000 | 987 |
| 100,001 – and over | 92 |
| | 3,671 |

(b) The number of shareholdings held in less than marketable parcels is 62 for ordinary shares.

(c) The names of the substantial shareholders listed in the holding company's register as at 30 July 2004 are:

Weighton Pty Ltd
MelanoTan Corporation USA

(d) Voting rights

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

(e) 20 Largest shareholders – ordinary shares

| | Name | Number of ordinary fully paid shares held | % Held of issued ordinary capital |
|---|---|---|---|
| 1 | Weighton Pty Ltd | 17,716,375 | 15.48 |
| 2 | MelanoTan Corporation USA | 15,165,415 | 13.25 |
| 3 | Merrill Lynch (Australia) Nominees Pty Ltd | 4,586.138 | 4.01 |
| 4 | ANZ Nominees Limited | 3,863,950 | 3.38 |
| 5 | Chartport Financial Services Pty Ltd | 3,312,805 | 2.89 |
| 6 | Citicorp Nominees Pty Limited | 2,899,894 | 2.53 |
| 7 | National Nominees Limited | 2,502,946 | 2.19 |
| 8 | Westpac Custodian Nominees Limited | 1,250,884 | 1.09 |
| 9 | Grunwald Design International Pty Ltd | 854,332 | 0.75 |
| 10 | Dr Helmer Agersborg | 750,000 | 0.66 |
| 11 | Mr Terrance Edwin Winters & Mrs Eilleen Young Winters | 750,000 | 0.66 |
| 12 | Mr Doug McLachlan & Mrs Wendy McLachlan | 680,000 | 0.59 |
| 13 | JFR Investments Pty Ltd | 663,228 | 0.58 |
| 14 | Mr Paul Joseph Pomerenke | 538,500 | 0.47 |
| 15 | Mr Cheng Han | 531,690 | 0.46 |
| 16 | Mr Trent Sheldon Redding | 505,600 | 0.44 |
| 17 | Lippo Securities Nominees | 505,000 | 0.44 |
| 18 | Chartport Pty Ltd | 500,000 | 0.44 |
| 19 | Seawise Nominees Pty Ltd | 434,503 | 0.38 |
| 20 | Manikato Financial Services | 420,000 | 0.37 |
| | | 58,431,260 | 51.06 |

## 2. COMPANY SECRETARY

The name of the company secretary is Iain Kirkwood.

## 3. REGISTERED OFFICE

The address of the principal registered office in Australia is Level 10, 52 Collins Street, Melbourne, Victoria, 3000, Telephone (03) 9662 4688.

## 4. REGISTER OF SECURITIES

Computershare Investor Services Pty Ltd
Level 12, 565 Bourke Street
Melbourne Victoria 3000

## 5. STOCK EXCHANGE LISTING

Quotation has been granted for all the ordinary shares of the company on all Member Exchanges of the Australian Stock Exchange Limited (ASX code: EPT).

## 6. RESTRICTED SECURITIES

Restricted securities on issue at 30 June 2004: Nil

# glossary

**αMSH** alpha-Melanocyte Stimulating Hormone is a peptide hormone which stimulates the production and release of melanin (melanogenesis) by melanocytes in the skin.

**GCP** Good Clinical Practice

**cGMP** Current good manufacturer practices. These practices are more fine tuned and up to date methodologies and procedures, mandated by regulatory authorities, which are to be followed in testing and manufacturer of pharmaceuticals to ensure the manufacture of safe clinical supplies.

**DNA** The molecule that carries genetic information in all living things; the chemical basis of heredity. Damaged DNA can lead to uncontrolled growth of cells which is commonly known as cancer.

**ELISA** Enzyme-Linked Immunosorbent Assay. A method of analyzing Melanotan in the blood of clinical trial subjects.

**EMEA** European Medicines Evaluation Agency. London based agency in Europe began in 1995. Co-ordinates drug licensing and safety through Europe.

**Eumelanin** The UV-protective dark pigment produced by melanocytes.

**FDA** United States Food & Drug Administration.

**Fitzpatrick skin type** Classification system based on a person's sensitivity to sunlight. People with skin types I and II are at the highest risk for photoaging effects including wrinkles and skin cancer.

**IND** Investigational New Drug. Companies seeking to begin clinical studies of a new pharmaceutical drug are required to lodge this application with the FDA.

**Keratinocytes** Skin cells that receive melanin from the melanocytes.

**Melanin** Produced by melanocytes, melanin is the natural substance that gives color (pigment) to skin.

**Melanocytes** The cells in the skin that produce melanin.

**Melanogenesis** The process whereby melanin is produced in the body.

**Phaeomelanin** The red-yellow non UV-protective pigment produced by melanocytes.

**Pharmacogenomics** The study of the interaction of an individual's genetic makeup and response to a drug

**Phase I** The first in a series of human tests of new pharmaceuticals. The primary purpose of the Phase I clinical test is to detect if the new pharmaceutical is toxic or otherwise harmful to normal, healthy humans. The conclusion of Phase I testing leads to Phase II and Phase III testing

**Phase II** The second in a series of human tests of new pharmaceuticals. The primary purpose of the Phase II clinical tests is to determine the pharmaceutical's efficacy (i.e., does it work?). Successful conclusion of Phase II tests allows Phase III clinical tests to begin

**Phase III** The third in a series of human tests of new pharmaceuticals. The primary purpose of Phase III clinical tests is to verify proper dosage of a new pharmaceutical

**PK** Pharmacokinetics - deals with what happens to a substance that is introduced into a living system e.g. how quickly it is broken down and what pathway it takes.

**PMLE** Polymorphous light eruption, is a skin disorder caused by sunlight. A delayed-onset, spotty, itchy eruption appears on the skin, and may take between 5 to 10 days to clear. The rash usually consists of small red spots or blisters and can appear on any part of the body that has been exposed to sunshine, although commonly the face and the backs of the hands will be spared. It tends to heal without scarring.

**Restoraderm®** A technology invented by Mr Thomas Sköld to transport molecules through the skin.

**Sustained-release** A process whereby the drug is released from a formulation over a long period of time.

**Tan** The body's natural response to protect itself from further skin damage caused by UV radiation.

**Topical** A cream, gel or spray applied to the skin.

**Vitiligo** Vitiligo (also called "leukoderma") is a skin condition in which there is loss of pigment from areas of the skin resulting in irregular white spots or patches, even though the skin has normal texture. Vitiligo may appear at any age. Although it is a progressive condition, many people experience years or decades without developing new spots. The cause of vitiligo is not greatly understood, and there may be many causes that result in the condition.

# corporate directory

**Registered Office**
Until Friday 3rd September:
Level 10, 52 Collins Street, Melbourne Victoria 3000 Australia

As from Monday 6th September:
Level 13, 1 Collins Street, Melbourne Victoria 3000 Australia
Telephone +61 3 9662 4688
Facsimile +61 3 9662 4788
Email mail@epitan.com.au
www.epitan.com.au

**Directors & Executives**

*Non Executive Directors*
Dr Helmer Agersborg (Deputy Chairman)
Dr Terry Winters
Stanley McLiesh

*Executive Chairman & Managing Director*
Dr Wayne Millen

*Chief Financial Officer & Company Secretary*
Iain Kirkwood

*Manager Clinical Development*
Dr Stuart Humphrey

*Manager Pharmaceutical & New Business Development*
Michael Kleinig

*Manager Pharmaceutical Products*
Chris Rossidis

*Manager Investor Relations & Marketing*
Davina Bridgeman

**Australian Stock Exchange**
The company's shares are quoted on the official list of the Australian Stock Exchange.

ASX Code: EPT

Level 1 American Depositary Receipt Code: EPTNY

**Auditor**
William Buck
Level 2, 215 Spring Street
Melbourne Australia 3000

**Banker**
National Australia Bank

**Lawyer**
Minter Ellison
Rialto Towers, 525 Collins Street
Melbourne 3000 Australia

**Share Registry**
Computershare Investor Services Pty Ltd
Yarra Falls, 452 Johnston Street
Abbotsford 3067 Australia
or
GPO Box 2975EE
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