

EpiTan Limited

**Annual General Meeting
2003**

Chairman's Report

Good morning ladies and gentlemen and welcome to EpiTan's 2003 Annual General Meeting.

Introduction

It is with great pleasure that I can report to you of your company's significant and exciting progress over the past 12 months. As Melanotan® continues to progress successfully through the clinical trial regime and we develop more user-friendly delivery formulations, local and international interest in EpiTan has increased considerably.

We believe this increased interest is warranted as your company has achieved much in the past 12 months.

This has resulted in our shareholder base increasing significantly from 1,300 12 months ago to over 3,000 registered shareholders today. Even more pleasing is the recognition of the potential value of our Melanotan drug through the increase in your company's share price from 11 cents with a market cap of \$9.5 million when I last addressed you at the 2002 AGM, to 73 cents at the close of trading yesterday - valuing EpiTan at \$81.5 million.

Since the end of May this year when our share price started to recover from below 20 cents, it has been volatile - influenced by excellent progress both on the clinical trial front and drug development, but tempered by some uncertainties in the market. Since May when we announced that the Phase IIb sunburn injury trials were showing promise our share price started to improve. The markets are now developing a greater appreciation of our clinical results and what this can mean to EpiTan's future. We are confident that, with this, a greater stability will occur in our valuation.

Key milestones achieved during the year

Before I talk about the exciting outlook for EpiTan, let me outline briefly the major developments over the last year.

- A sustained-release implant formulation was developed in collaboration with Southern Research Institute, of Alabama in the USA. This new formulation is a small implant or pellet, designed to be placed under the skin. It is made of the same material that has been used for many years in “self-dissolving” stitches and is therefore known to be safe and reliable. As the implant is totally biodegradable it does not have to be removed at the end of the treatment. The formulation is a major advancement on the daily protocol of injections which were used in our Phase IIb clinical trial and which finished in September. From now on, future trials will use these implants and this is what we expect to be available on the market first. The implants will commence clinical trials in November at the Q-Pharm human trial facility in Queensland.
- In June this year EpiTan signed a strategic collaborative agreement with Thomas Sköld of Sweden and CollaGenex Pharmaceuticals Inc. of Pennsylvania in the USA, to develop a lotion or gel topical formulation.

Given previous technology was unable to achieve this objective, we believe that Mr Sköld’s Restoraderm technology improves the feasibility of developing a topical formulation for Melanotan.

We have brought in Melbourne’s Monash University and the Institute of Medical and Veterinary Science (IMVS), based in Adelaide, to work with Mr Sköld. The company believes these collaborative arrangements will lead to a faster development of a formulation for topical application and we expect to have a prototype ready for testing by mid-2004.

- In September we signed a collaborative agreement pSivida, a Perth-based nanotechnology company which is listed on the ASX.

The agreement aims to develop a new liquid-based sustained release method of administration for Melanotan incorporating pSivida's BioSilicon™ nanotechnology. We consider this is an outstanding opportunity to combine Melanotan with this new sophisticated nanotechnology. Initial proof-of-concept studies are expected to be completed by the end of this year.

We are always looking to the future and the outcome of this work could lead to a second-generation Melanotan product. As this product would be a liquid-based sustained-release product delivered via a single dose of approximately 0.5ml, it would give consumers further choice as to how they could have Melanotan administered. In the future, conceivably, consumers could choose between an implant, a liquid injection or a topical application.

- You will have noticed that, earlier this week, we announced the results of our Phase IIb trial. The results supported the interim announcement made by the company in May of this year outlining that very encouraging levels of melanin production had emerged from the trial.

Due to the likelihood of patent applications emerging from this study, full disclosure of the data cannot yet be made. However, key information that can be revealed is that:

- Clinically visible tanning was noted in a large proportion of volunteers;
- The difference between the Melanotan-treated group and the placebo group was highly significant at all skin sites measured.
- Importantly, the percentage increase in melanin density for fairer skin types (Fitzpatrick I/II) was approximately double that for those with darker skin types (Fitzpatrick III/IV).

- Only 6 volunteers, or 7.4% of the total, thought they had Fitzpatrick Skin Type I, (which means they always burn and never tan). After being measured clinically, 29 or 35.8% were assessed by the Investigators as Skin Type I. The inference is that Australians overestimate their in-built skin protection levels, and that consequently, they need more protection than they think they do.

The key data regarding these volunteers with fairer skin types confirms that Melanotan may be effectively used as a prescription sunscreen to provide protection against both Ultraviolet A (UVA) and Ultraviolet B sunlight (UVB). It is a significant benefit to these people who normally produce little melanin and consequently are most at risk of sunburn injury.

- FDA IND meeting

Your company also announced recently that we had completed a meeting with the Food and Drug Administration in the USA. The meeting was a “pre-IND discussion meeting” requested by the company for the purpose of reviewing EpiTan’s proposal to submit a formal Investigational New Drug (“IND”) application. An IND application must be submitted to a regulatory agency (the FDA in the United States) before a drug can be studied in humans and, accordingly, is a prerequisite to starting (human) clinical trials.

We are conscious that the market is anticipating an announcement concerning the result of this meeting. However, as previously stated, we cannot make a definitive announcement until we have received the formal FDA minutes of the meeting.

- Financially, EpiTan is in good shape. In the period between the end of June and August we successfully raised over \$10 million to secure our immediate financial position. Firstly as our share price reached 30 cents just before the end of June, we received \$2.7 million from the exercise

of our listed 30 June 2003 options. Secondly, your directors decided to take advantage of the strong surge in the company's share price which reacted positively to the excellent pipeline of progress I have just detailed above. A placement of 14,500,000 shares was successfully completed to institutional and sophisticated investors at 51 cents per share, raising \$7.4 million.

The funds raised will be used to expand and accelerate the company's clinical trial programme including the addition of studies in the USA and Europe in 2004 and a genotype study in Australia to identify the skin cancer risk among Caucasians. Additional volumes of drug and implants will also be manufactured to support this acceleration and expansion of the company's clinical trial strategy.

Why Melanotan is such an important breakthrough in skin management

As a background to EpiTan's core endeavours I would like to review for you the origin of the Melanotan project and where we see its place in the important world of skin protection.

Sunlight arrives on earth in three forms: infrared (heat), visible and ultraviolet (UV) light, with UV light being classified into three categories:

- The first is UVA, which is also known as black light, which causes tanning
- The second is UVB which causes damage in the form of sunburn
- The third is UVC which is filtered out by the atmosphere and never reaches us.

99% of the sun's UV radiation at sea level is UVA. It is the UVB that causes things like reddening, aging, wrinkles, and some skin cancers. Research is increasingly implicating UVA as the main cause of melanoma.

One of the interesting things about UV radiation is that it is reflected by different surfaces. These reflections can amplify the effects of UV exposure. For example, snow reflects 90% of UV light. That is why you can get snow blindness and severe sunburns from skiing on a sunny day. Sand can reflect up to 20% of UVB that hits it, meaning that you can get extra UV exposure at the beach.

On the other hand, certain things absorb almost all UV radiation partially or completely. Glass is one of these substances - many glasses are very good absorbers of UV (which is why you may have heard that you cannot get sunburn in a greenhouse). Most sunscreens use chemicals that have the same UV-absorbing properties.

As a flow on from this, much is known regarding the harmful effects of UV radiation on the skin. Increasing research continues to highlight the real danger of the impact of sun exposure and other sources of UV radiation upon particularly fair skinned populations. At EpiTan we believe that Melanotan will prove to be a crucial breakthrough as a photo-protective tool.

Melanotan can be safely used in the fight against sunburn injury particularly for those people who have fair skin types. To date nothing other than stronger and more broad-spectrum sunscreens have been available to assist with sun protection.

Until Melanotan becomes available, the current, practical steps to achieve optimal sun protection other than simply not going out into the sun, are wearing photo-protective clothing or diligent application of broad-spectrum sunscreens. However, notwithstanding the availability of sunscreens for many years, the incidence of skin cancer is increasing and melanoma cases are, for example, rising faster than any other type of cancer in, of all places, the UK.

Scientists there are warning of a possible epidemic in young women, especially those who seek the all-fashionable tanned look. The results of the recently completed Phase IIb trial show that Melanotan will preferentially assist those genotypes with fair skin and therefore with a higher predisposition to skin cancer by increasing their in-built "SPF" factor. Importantly, melanin protects against both UVB and UVA, something not all sunscreens afford.

We know that when you get a tan, what is actually happening is that the melanocytes are producing melanin pigment in reaction to UV light in sunlight. Melanin pigment has the effect of absorbing the UV radiation in sunlight, so it protects the cells from UV damage. But the real problem is that melanin production takes a fair amount of time - that is why most people cannot get a tan in one day, and most fair skin people burn first. You have to first expose yourself to UV for a period of time to activate the melanocytes for them to produce melanin over the course of hours. By repeating this process over 5 to 7 days pigment builds up in your cells to a level that is protective. Unfortunately, during this time of melanin build up, the skin is vulnerable to damage.

It is against this background that Melanotan has its profound effect by enabling the skin to produce the natural melanin pigment. By engineering melanin production with Melanotan prior to exposure to UV radiation the body is able to counteract the full damaging effects of UV when subsequently exposed to it.

Melanotan is one of the series of drugs now categorised in the new area of "Pharmacogenomics".

As Australia's most recent Nobel Prize laureate, Dr Peter Doherty, stated in The Australian this month, "The new science of genomics will also lead to dramatic improvements in the way diseases are diagnosed and treated. Knowing the sequence of the whole human genome has given us new, rapid,

DNA array technologies that can be used to identify abnormal patterns of gene read-out in cancer cells and to determine which genetic profiles are associated with increased risk”.

At EpiTan we have, through our recent Phase IIb clinical trials, been able to determine that Melanotan can selectively enhance the melanin production capability of those pale-skinned people who previously burnt in the sun and could not tan easily. This is the only drug ever to have an effect on these individuals with a propensity to develop skin cancer, and our ongoing work in this area is groundbreaking.

Therapeutic applications for Melanotan

Now that our financial position is more secure, the company can expand its clinical trial strategy to include therapeutic indications such as polymorphous light eruption, which is a significant UV-induced skin allergy in northern latitudes. It is estimated that between 10-20% of the population of North America, Britain and Scandinavia suffer from PMLE in spring and early summer. We are becoming increasingly confident from our studies that Melanotan can be used to address this and other sun-induced skin disorders.

A vitiligo study is also planned once the topical formulation is ready.

Outlook for Remaining 2003 and 2004

Our clinical programme is planned to continue with even greater momentum both in Australia and overseas during the coming year.

In November our implant trials will get underway at the Queensland Institute of Medical Research in Brisbane.

The start of PMLE trials is scheduled for the second quarter of 2004, probably in Germany.

The IND submission to the FDA to commence trials in the USA is also scheduled for the second quarter of 2004.

Commencement of the genotype study at the Queensland Institute of Medical Research and the sunburn injury trials in the USA are planned for the third quarter of 2004.

Following the excellent results from our clinical programmes, the understanding that Melanotan represents the first, and to our understanding the only drug that can deliver control over "Melanogenesis", the body's melanin production, is now being digested by the financial and scientific communities. As our clinical programmes evolve in Europe and the USA, and as the significance of the beneficial medical implications of Melanotan for millions around the globe becomes better appreciated, there will be a larger impact on the valuation of EpiTan.

To date, we firmly believe that we don't have a better mousetrap - we have the mousetrap.

It is a significant fact that Epitan is one of a select few biotech companies in Australia with a drug having completed a Phase II trial.

In conclusion, I thank you our shareholders and stakeholders for the patience you have shown as EpiTan has evolved under difficult market forces over the last year. I can assure you the next 12 months will be more exciting than the last, and I seek your continuing support.

I personally have enjoyed, and have been invigorated by my many contacts and discussions with you and look forward to continuing with the interactions this coming year.

I also extend my thanks to my fellow directors whose support and valuable guidance is always welcome, and is always readily available. The demands

on them will be even greater in this coming year as we look ever increasing overseas to the global markets for our destiny.

Finally, a special tribute to the team at EpiTan who continue to work tirelessly to make our company a success. There are only six of them, and they achieved much in the past year. Their quest for the holy grail of commercialisation of Melanotan is infectious and compelling. It is a pleasure to stand here today, as part of that team in pursuit of what is fast becoming a realistic event.

Thank you.