ReedSmith



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August 19, 2004

**VIA FEDERAL EXPRESS**

Office of International Corporate Finance
Division of Corporate Finance
Mail Stop 3-2
Securities and Exchange Commission
Judiciary Plaza
450 Fifth Street, N.W.
Washington, D.C. 20549



Re: File No. 82-34790

Ladies and Gentlemen:

On behalf of EpiTan Limited (the "**Company**") we hereby furnish this letter to the Securities and Exchange Commission (the "**SEC**") in order to provide you information that has been made public, distributed or filed with the Australian Stock Exchange Limited (the "**ASX**") or the Australian Securities and Investments Commission (the "**ASIC**") by the Company in connection with the its ongoing obligation to furnish such information to the SEC pursuant to its Rule 12g3-2(b) exemption.

Enclosed under Exhibit A attached to this letter is a complete list and copy of information that the Company has (i) made public or is required to make public pursuant to the Corporations Act of Australia; (ii) distributed or is required to distribute to the holders of its securities; and (iii) filed or is required to file with the ASX or ASIC since the date of its initial submission.

The Company agrees that it will continue to furnish to the SEC on an ongoing basis whatever information it makes public, distributes or files with the ASX or the ASIC.

If you have any questions or comments please call me at 212.549.0246 or Ms. Maria Tripodes at 212.549.0202.

To confirm your receipt of the enclosed material, please file stamp the enclosed copy of this letter and return it in the pre-addressed envelope also enclosed herewith.

Sincerely,

Antone P. Manha

8/23

**FILE NO. 82-34790**

**EXHIBIT A**

| DOCUMENT | DESCRIPTION |
|---|---|
| 1 | Company announcement, dated August 12, 2004 |
| 2 | Company announcement, dated August 11, 2004 |
| 3 | Appendix 4C, Quarterly report for entities admitted on the basis of commitments, dated July 27, 2004 |
| 4 | Appendix 3B and 3Y, New issue announcement, dated July 23, 2004 |
| 5 | Company announcement, dated July 19, 2004 |
| 6 | Company announcement, dated July 6, 2004 |
| 7 | Company announcement, dated July 1, 2004 |
| 8 | Change of Directors Interest Appendix 3Y and Form 604, dated June 28, 2004 |
| 9 | Open Briefing, EpiTan Chairman & CFO on Strategy and Outlook, dated June 16, 2004 |
| 10 | BBY Report Amendment, dated May 31, 2004 |
| 11 | Appendix 3Y, dated May 31, 2004 |
| 12 | Appendix 3B, dated May 31, 2004 |
| 13 | Company announcement, dated May 6, 2004 |

company announcement

Thursday 12 August 2004

# *EpiTan files provisional patent in the United States*

For more information contact
Davina Bridgeman, Investor Relations & Marketing, EpiTan Limited, Telephone +61 3 9662 4688
Richard Allen, Oxygen Financial Public Relations, Telephone +61 3 9915 6341
investorrelations@epitan.com.au

Melbourne, Australia

EpiTan Limited (ASX: EPT, ADR: EPTNY) today announced that it has filed a provisional patent with the United States Patent and Trademark Office encompassing the discoveries and unexpected results from preliminary data obtained in the recent Melanotan sustained release clinical trial.

Michael Kleinig, EpiTan's Pharmaceutical and New Business Development Manager, said: "This patent application was filed to protect the use of Melanotan in all anticipated delivery formulations. This means that no one else would be able to commercialise Melanotan, in a sustained release delivery formulation, irrespective of whether it is delivered by an implant, topically, orally (a pill), or other, for 20 years."

Dr Wayne Millen, EpiTan's Executive Chairman and CEO, said: "The increased protection for EpiTan is significant. If this patent is granted it will be very difficult for any potential competitor to develop and bring to market, a commercially viable alternative. An independent report has identified that the market for Melanotan is likely to be very lucrative. Accordingly we continue to enhance our intellectual property position."

EpiTan's intellectual property counsel confirmed that this patent application, if granted, would considerably strengthen EpiTan's IP portfolio. The patent application has the potential for a further 20 years of market exclusivity for EpiTan, from the filing date, regarding the use of Melanotan to increase the levels of melanin in the skin via sustained release delivery methods.



**EpiTan Limited** abn 88 089 644 119
Level 10, 52 Collins Street Melbourne Victoria 3000 Australia **Telephone** +61 3 9662 4688 **Facsimile** +61 3 9662 4788 www.epitan.com.au

**About EpiTan Limited**

EpiTan Limited is a Melbourne-based specialty pharmaceutical company with a focus on niche prescription dermatology products. Its leading drug candidate Melanotan® stimulates the body to make melanin, the dark pigment of a tan which 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 three products - 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.

About Melanotan

Melanotan has completed a Phase II clinical trial in Australia that demonstrated the drug increases melanin content 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. These trials will assess its potential both as a preventative to reduce the effects of UV damage and 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 identified 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.

**-END-**



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company announcement

Wednesday 11 August 2004

## *Private Placement Raises A$7.98 million*

For more information contact:
Davina Bridgeman, Investor Relations & Marketing, EpiTan Limited, Telephone +61 3 9662 4688
Richard Allen, Oxygen Financial Public Relations, Telephone +61 3 9915 6341
investorrelations@epitan.com.au

Melbourne, Australia

EpiTan Limited (ASX: EPT, ADR: EPTNY) today announced that it has raised A$7.98 million from two European-based investors.

The capital was raised via a private placement of 10,500,000 fully paid ordinary shares at A$0.76. EpiTan Limited also issued 6,667,362 unlisted options exercisable over three years at A$1.03 which, on exercise, would result in a further cash injection of A$6.87 million.

The average price for this transaction is A$0.85c which represents a 6.4% discount to the three-month Volume Weighted Average Price (VWAP) of A$0.91 and a discount of 3.8% to the six-month VWAP of A$0.88.

A total of 8,500,000 shares were placed with the Absolute Return Europe Fund managed by FM Fund Management Limited (www.fmlimited.com). A further 2,000,000 shares were placed with Mercury Investments Limited, based in the UK.

Absolute Return Europe Fund now becomes a substantial shareholder in EpiTan, with 6.8% of the company's shares.

The unlisted options have been allocated between Absolute Return Europe Fund and Mercury Investments Limited, in the amount of 4,048,041 and 2,619,321 options respectively.

FM Fund Management Limited is a specialist fund manager with operations in Switzerland, Spain, Germany and the Americas. The firm's lead manager and majority shareholder is



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Florian Homm, a renowned European investor and a specialist in life sciences. Mr. Homm has won several major investment awards from agencies such as Lipper, Micropal, S&P, Morningstar and Finanzen.

Mercury Investments Limited is an international investment fund based in London and incorporated in Hong Kong that focuses on identifying and investing in undervalued companies in the biotechnology and information technology sectors, which have promising products and technologies. Rohit Bhoothalingam, a spokesman for MIL, said: "We believe EpiTan represents a very exciting investment opportunity based on a combination of its current market valuation, the potential of its existing technologies especially the Melanotan product and the potential size of its customer market."

Dr Wayne Millen, EpiTan's Executive Chairman and CEO, said: "We are delighted to welcome two large institutional shareholders of the calibre of FM Fund Management and Mercury Investments to our share register. EpiTan's cash reserves now total approximately A$13 million and our collaborative partnering discussions are active and progressing well."

Dr Millen added: "Recent pre clinical results from the testing of one of our topical formulations were both unexpected and highly encouraging. As a consequence, EpiTan is now in the process of re-assessing its clinical trial strategy for both the subcutaneous implant and topical formulation. Details are expected to be finalised in the next few weeks."

**About EpiTan Limited**

EpiTan Limited is a Melbourne-based specialty pharmaceutical company with a focus on niche prescription dermatology products. Its leading drug candidate Melanotan® stimulates the body to make melanin, the dark pigment of a tan which 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 three products 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.

About Melanotan

Melanotan has completed a Phase II clinical trial in Australia that demonstrated increases in melanin content by up to 100% and reduction in 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. These trials will assess its potential both as a preventative to reduce the effects of UV damage and as a therapy for UV-associated skin disorders such as polymorphous light eruption (PMLE).



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**-END-**



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*Rule 4.7B*

# Appendix 4C

## Quarterly report for entities admitted on the basis of commitments

Introduced 31/3/2000. Amended 30/9/2001

Name of entity

EPITAN LIMITED

ABN

88 089 644 119

Quarter ended ("current quarter")

30 JUNE 2004

## Consolidated statement of cash flows

| | | | Current quarter $A'000 | Year to date (12 months) $A'000 |
|---|---|---|---|---|
| **Cash flows related to operating activities** | | | | |
| 1.1 | Receipts from customers | | - | - |
| 1.2 | Payments for | (a) staff costs | (74) | (453) |
| | | (b) advertising and marketing | - | - |
| | | (c) research and development | (1,115) | (4,921) |
| | | (d) leased assets | - | - |
| | | (e) other working capital | (566) | (1,258) |
| 1.3 | Dividends received | | | |
| 1.4 | Interest and other items of a similar nature received | | 100 | 344 |
| 1.5 | Interest and other costs of finance paid | | - | - |
| 1.6 | Income taxes paid | | - | - |
| 1.7 | Other (GST refunds) | | 76 | 285 |
| | **Net operating cash flows** | | (1,579) | (6,003) |

+ See chapter 19 for defined terms.

**Appendix 4C**
**Quarterly report for entities admitted on the basis of commitments**

| | | Current quarter $A'000 | Year to date (12 months) $A'000 |
|---|---|---|---|
| 1.8 | Net operating cash flows (carried forward) | **(1,579)** | **(6,003)** |
| | **Cash flows related to investing activities** | | |
| 1.9 | Payment for acquisition of: | | |
| | (a) businesses (item 5) | - | - |
| | | - | - |
| | (b) equity investments | - | (27) |
| | (c) intellectual property | - | - |
| | | (1) | (15) |
| | (d) physical non-current assets | - | - |
| | (e) other non-current assets | | |
| 1.10 | Proceeds from disposal of: | | |
| | (a) businesses (item 5) | - | - |
| | (b) equity investments | - | - |
| | (c) intellectual property | - | - |
| | (d) physical non-current assets | - | - |
| | (e) other non-current assets | - | - |
| 1.11 | Loans to other entities | - | - |
| 1.12 | Loans repaid by other entities | - | - |
| 1.13 | Other (provide details if material) | - | - |
| | **Net investing cash flows** | (1) | (42) |
| **1.14** | **Total operating and investing cash flows** | (1,580) | (6,045) |
| | **Cash flows related to financing activities** | | |
| 1.15 | Proceeds from issues of shares, options, etc. | 355 | 9,793 |
| 1.16 | Proceeds from sale of forfeited shares | - | - |
| 1.17 | Proceeds from borrowings | - | - |
| 1.18 | Repayment of borrowings | - | - |
| 1.19 | Dividends paid | - | - |
| 1.20 | Other (fundraising costs) | - | (880) |
| | **Net financing cash flows** | 355 | 8,913 |
| | **Net increase (decrease) in cash held** | (1,225) | 2,868 |
| 1.21 | Cash at beginning of quarter/year to date | 6,705 | 2,612 |
| 1.22 | Exchange rate adjustments to item 1.20 | | |
| 1.23 | **Cash at end of quarter** | 5,480 | 5,480 |

+ See chapter 19 for defined terms.

## Payments to directors of the entity and associates of the directors

## Payments to related entities of the entity and associates of the related entities

| | | Current quarter $A'000 |
|---|---|---|
| 1.24 | Aggregate amount of payments to the parties included in item 1.2 | 70 |
| 1.25 | Aggregate amount of loans to the parties included in item 1.11 | - |

1.26 Explanation necessary for an understanding of the transactions

| |
|---|
| |

## Non-cash financing and investing activities

2.1 Details of financing and investing transactions which have had a material effect on consolidated assets and liabilities but did not involve cash flows

| |
|---|
| |

2.2 Details of outlays made by other entities to establish or increase their share in businesses in which the reporting entity has an interest

| |
|---|
| |

## Financing facilities available

*Add notes as necessary for an understanding of the position. (See AASB 1026 paragraph 12.2).*

| | | Amount available $A'000 | Amount used $A'000 |
|---|---|---|---|
| 3.1 | Loan facilities | | |
| 3.2 | Credit standby arrangements | | |

+ See chapter 19 for defined terms.

**Appendix 4C**
**Quarterly report for entities**
**admitted on the basis of commitments**

## Reconciliation of cash

| Reconciliation of cash at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts is as follows. | | Current quarter $A'000 | Previous quarter $A'000 |
|---|---|---|---|
| 4.1 | Cash on hand and at bank | 171 | 343 |
| 4.2 | Deposits at call | 1,315 | 2,386 |
| 4.3 | Bank overdraft | - | - |
| 4.4 | Other (bank bills and income security notes) | 3,994 | 3,976 |
| | **Total: cash at end of quarter** (item 1.22) | 5,480 | 6,705 |

## Acquisitions and disposals of business entities

| | | Acquisitions *(Item 1.9(a))* | Disposals *(Item 1.10(a))* |
|---|---|---|---|
| 5.1 | Name of entity | - | - |
| 5.2 | Place of incorporation or registration | - | - |
| 5.3 | Consideration for acquisition or disposal | - | - |
| 5.4 | Total net assets | - | - |
| 5.5 | Nature of business | - | - |

## Compliance statement

1 This statement has been prepared under accounting policies which comply with accounting standards as defined in the Corporations Act (except to the extent that information is not required because of note 2) or other standards acceptable to ASX.

2 This statement does /~~does not~~* *(delete one)* give a true and fair view of the matters disclosed.

Sign here:  Date: 27 July 2004

(~~Director~~/Company secretary)

Print name: Iain Kirkwood.

+ See chapter 19 for defined terms.

Rule 2.7, 3.10.3, 3.10.4, 3.10.5

# Appendix 3B

## New issue announcement, application for quotation of additional securities and agreement

*Information or documents not available now must be given to ASX as soon as available. Information and documents given to ASX become ASX's property and may be made public.*

Introduced 1/7/96. Origin: Appendix 5. Amended 1/7/98, 1/9/99, 1/7/2000, 30/9/2001, 11/3/2002, 1/1/2003.

Name of entity

EPITAN LIMITED

ABN

88 089 644 119

We (the entity) give ASX the following information.

## Part 1 - All issues

*You must complete the relevant sections (attach sheets if there is not enough space).*

| | | |
|---|---|---|
| 1 | +Class of +securities issued or to be issued | Ordinary Shares |
| 2 | Number of +securities issued or to be issued (if known) or maximum number which may be issued | 145,846 ordinary shares |
| 3 | Principal terms of the +securities (eg, if options, exercise price and expiry date; if partly paid +securities, the amount outstanding and due dates for payment; if +convertible securities, the conversion price and dates for conversion) | Exercise of 145,846 unquoted (directors) options at 30 cents each |

+ See chapter 19 for defined terms.

**Appendix 3B**
**New issue announcement**

| | | |
|---|---|---|
| 4 | Do the +securities rank equally in all respects from the date of allotment with an existing +class of quoted +securities?<br><br>If the additional securities do not rank equally, please state:<br>• the date from which they do<br>• the extent to which they participate for the next dividend, (in the case of a trust, distribution) or interest payment<br>• the extent to which they do not rank equally, other than in relation to the next dividend, distribution or interest payment | Yes |
| 5 | Issue price or consideration | Total $43,753.80 |
| 6 | Purpose of the issue<br>(If issued as consideration for the acquisition of assets, clearly identify those assets) | Exercise of 145,846 unquoted (directors) options |
| 7 | Dates of entering +securities into uncertificated holdings or despatch of certificates | 26 April 2004 |

8 Number and +class of all +securities quoted on ASX (*including* the securities in clause 2 if applicable)

| Number | +Class |
|---|---|
| 114,449,085 EPT | ordinary |

+ See chapter 19 for defined terms.

**Appendix 3B**
**New issue announcement**

| | | Number | +Class |
|---|---|---|---|
| 9 | Number and +class of all +securities not quoted on ASX (*including* the securities in clause 2 if applicable) | 5,616,556 | EpiTan Incentive Option Plan |

| | | |
|---|---|---|
| 10 | Dividend policy (in the case of a trust, distribution policy) on the increased capital (interests) | Ordinary shares ranking equally with existing ordinary shares |

## Part 2 - Bonus issue or pro rata issue

| | | |
|---|---|---|
| 11 | Is security holder approval required? | |
| 12 | Is the issue renounceable or non-renounceable? | |
| 13 | Ratio in which the +securities will be offered | |
| 14 | +Class of +securities to which the offer relates | |
| 15 | +Record date to determine entitlements | |
| 16 | Will holdings on different registers (or subregisters) be aggregated for calculating entitlements? | |
| 17 | Policy for deciding entitlements in relation to fractions | |
| 18 | Names of countries in which the entity has +security holders who will not be sent new issue documents<br>Note: Security holders must be told how their entitlements are to be dealt with.<br>Cross reference: rule 7.7. | |
| 19 | Closing date for receipt of acceptances or renunciations | |

+ See chapter 19 for defined terms.

**Appendix 3B**
**New issue announcement**

| | | |
|---|---|---|
| 20 | Names of any underwriters | |
| 21 | Amount of any underwriting fee or commission | |
| 22 | Names of any brokers to the issue | |
| 23 | Fee or commission payable to the broker to the issue | |
| 24 | Amount of any handling fee payable to brokers who lodge acceptances or renunciations on behalf of +security holders | |
| 25 | If the issue is contingent on +security holders' approval, the date of the meeting | |
| 26 | Date entitlement and acceptance form and prospectus or Product Disclosure Statement will be sent to persons entitled | |
| 27 | If the entity has issued options, and the terms entitle option holders to participate on exercise, the date on which notices will be sent to option holders | |
| 28 | Date rights trading will begin (if applicable) | |
| 29 | Date rights trading will end (if applicable) | |
| 30 | How do +security holders sell their entitlements *in full* through a broker? | |
| 31 | How do +security holders sell *part* of their entitlements through a broker and accept for the balance? | |

+ See chapter 19 for defined terms.

| | | |
|---|---|---|
| 32 | How do +security holders dispose of their entitlements (except by sale through a broker)? | |
| 33 | +Despatch date | |

# Part 3 - Quotation of securities

*You need only complete this section if you are applying for quotation of securities*

34 Type of securities
(*tick one*)

(a) ☒ Securities described in Part 1

(b) ☐ All other securities

Example: restricted securities at the end of the escrowed period, partly paid securities that become fully paid, employee incentive share securities when restriction ends, securities issued on expiry or conversion of convertible securities

## Entities that have ticked box 34(a)

### Additional securities forming a new class of securities

*Tick to indicate you are providing the information or documents*

35 ☐ If the +securities are +equity securities, the names of the 20 largest holders of the additional +securities, and the number and percentage of additional +securities held by those holders

36 ☐ If the +securities are +equity securities, a distribution schedule of the additional +securities setting out the number of holders in the categories
1 - 1,000
1,001 - 5,000
5,001 - 10,000
10,001 - 100,000
100,001 and over

37 ☐ A copy of any trust deed for the additional +securities

+ See chapter 19 for defined terms.

**Appendix 3B**
**New issue announcement**

## Entities that have ticked box 34(b)

| | | |
|---|---|---|
| 38 | Number of securities for which +quotation is sought | |
| 39 | Class of +securities for which quotation is sought | |
| 40 | Do the +securities rank equally in all respects from the date of allotment with an existing +class of quoted +securities?<br><br>If the additional securities do not rank equally, please state:<br>• the date from which they do<br>• the extent to which they participate for the next dividend, (in the case of a trust, distribution) or interest payment<br>• the extent to which they do not rank equally, other than in relation to the next dividend, distribution or interest payment | |
| 41 | Reason for request for quotation now<br><br>Example: In the case of restricted securities, end of restriction period<br><br>(if issued upon conversion of another security, clearly identify that other security) | |
| 42 | Number and +class of all +securities quoted on ASX (*including* the securities in clause 38) | Number: <br> +Class: |

+ See chapter 19 for defined terms.

**Quotation agreement**

1 +Quotation of our additional +securities is in ASX's absolute discretion. ASX may quote the +securities on any conditions it decides.

2 We warrant the following to ASX.

- The issue of the +securities to be quoted complies with the law and is not for an illegal purpose.
- There is no reason why those +securities should not be granted +quotation.
- An offer of the +securities for sale within 12 months after their issue will not require disclosure under section 707(3) or section 1012C(6) of the Corporations Act.

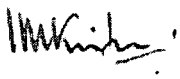
  Note: An entity may need to obtain appropriate warranties from subscribers for the securities in order to be able to give this warranty

- Section 724 or section 1016E of the Corporations Act does not apply to any applications received by us in relation to any +securities to be quoted and that no-one has any right to return any +securities to be quoted under sections 737, 738 or 1016F of the Corporations Act at the time that we request that the +securities be quoted.
- We warrant that if confirmation is required under section 1017F of the Corporations Act in relation to the +securities to be quoted, it has been provided at the time that we request that the +securities be quoted.
- If we are a trust, we warrant that no person has the right to return the +securities to be quoted under section 1019B of the Corporations Act at the time that we request that the +securities be quoted.

**Appendix 3B**
**New issue announcement**

3 We will indemnify ASX to the fullest extent permitted by law in respect of any claim, action or expense arising from or connected with any breach of the warranties in this agreement.

4 We give ASX the information and documents required by this form. If any information or document not available now, will give it to ASX before +quotation of the +securities begins. We acknowledge that ASX is relying on the information and documents. We warrant that they are (will be) true and complete.

Sign here:  Date: 23 July 2004

(~~Director~~/Company secretary)

Print name: I.M. Kirkwood

== == == == ==

+ See chapter 19 for defined terms.

company announcement

Monday 19 July, 2004

# *EpiTan acquires three dermatology products*

For more information contact
Davina Bridgeman, Investor Relations & Marketing, EpiTan Limited, Telephone +61 3 9662 4688
Richard Allen, Oxygen Financial Public Relations, Telephone +61 3 9915 6341
investorrelations@epitan.com.au

Melbourne, Australia

EpiTan Limited (ASX: EPT) today announced that it has acquired three products as part of its strategy to establish a specialty pharmaceutical business focused on dermatology.

Two of the products, Linotar® and Exorex®, are already registered and generating sales in Australia and the third, Zindaclin®, has been submitted to the TGA for registration.

Linotar, for the treatment of eczema, and Exorex, for the treatment of psoriasis, were acquired from TransDermal Pharmaceuticals Australia Pty Limited. Zindaclin, a unique, once-a-day clindamycin-based gel for the treatment of acne, has been in-licensed from UK based Strakan Pharmaceuticals. Financial terms of the acquisitions are confidential.

Linotar and Exorex have significant potential for growth in a market currently valued at more than A$10 million. The size of the anti-acne market in Australia for Zindaclin is estimated to be worth approximately A$12 million.

"These acquisitions will help launch EpiTan's dermatology sales and marketing operation effective as of July 2004, and we expect sales revenues to exceed A$3 million in 2005/06," said Dr Wayne Millen, EpiTan's Executive Chairman and CEO. "Other acquisitions and in-licensing product opportunities are also being actively pursued to provide future growth in sales. We are confident the primary driver for future growth will be our leading drug candidate, Melanotan®, which is on track to be launched in late 2006 or early 2007."



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Current independent estimates of Melanotan's sales for Australia and New Zealand alone are expected to reach in excess of A$50 million in the first two years, which underpins very strong growth prospects for EpiTan over the next five years.

Chris Rossidis, Manager Pharmaceutical Products, said, "EpiTan is exploiting a unique opportunity to develop the only listed pharmaceutical company in Australia with a focus on niche prescription dermatology products."

**About EpiTan**

Melbourne-based pharmaceutical company EpiTan Limited has the worldwide rights to develop 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, a known prime cause of skin cancer. Simply, Melanotan induces a protective tan without the need to expose skin to harmful levels of UV radiation.

EpiTan completed a Phase IIb clinical trial in 2003 which demonstrated that Melanotan 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 shortly undergo clinical studies in Europe to assess its potential as a therapy for UV-associated skin disorders such as polymorphous light eruption (PMLE).

Melanotan will likely be administered by a user-friendly and biodegradable sustained-release implant, administered by injection. Transdermal formulations, such as a lotion, spray and patch are also being developed.

The global dermatology market is estimated at US$2.5bn and the solarium market is worth in excess of US$5bn in the US alone.

**-END-**



**EpiTan Limited** abn 88 089 644 119
Level 10, 52 Collins Street Melbourne Victoria 3000 Australia **Telephone** +61 3 9662 4688 **Facsimile** +61 3 9662 4788 www.epitan.com.au

epitan

Tuesday 6 July 2004

Company Announcement

# Sustained-release clinical trial resumed with new smaller implant

For more information contact:
Davina Bridgeman, Investor Relations & Marketing, EpiTan Limited, Tel: +61 3 9662 4688
Richard Allen, Oxygen Financial Public Relations, Tel: +61 4 0349 3049
investorrelations@epitan.com.au
www.epitan.com.au

Melbourne, Australia

EpiTan Limited (ASX:EPT) today confirmed that the Melanotan® sustained release implant trial has resumed with a new significantly smaller solid injectable. The trial is being conducted at Q-Pharm, based at the Clive Berghofer Cancer Research Centre in Queensland.

The key objective of this trial is to confirm the optimal dose for the sustained-release formulation, as well as its safety and efficacy. Following the better-than-expected efficacy of the previous larger implant announced in February 2004, the trial was rescheduled pending the production of a new batch of smaller implants containing considerably less drug.

"We have developed a more user-friendly formulation of Melanotan," said Dr Wayne Millen, EpiTan's Executive Chairman and CEO. "This new implant is smaller and can be injected with a 16 gauge needle. This translates to a product that will be more acceptable to the individual as well as more cost effective."

Volunteers will receive escalating doses of the new sustained-release formulation over the coming months, with results expected in Q4 2004. The solid injectable formulation is made from the same material as used in self-dissolving stitches 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.

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

**About EpiTan**:

Melbourne-based biotechnology company EpiTan Limited has the worldwide rights to develop Melanotan which stimulates the body to make melanin. Melanin is known to protect the body from skin damage as a result of sunburn, a known prime cause of skin cancer. Simply, Melanotan induces a protective tan without exposure to harmful levels of UV radiation.

EpiTan has completed a Phase IIb clinical trial which demonstrated that Melanotan increases melanin content in the skin by up to 100% and reduces sunburn injury by up to 50% in fair-skinned volunteers, representing a significant breakthrough for people most at risk of sunburn injury and skin cancer. Melanotan will shortly undergo clinical studies to assess its potential as a therapy for UV-associated skin disorders such as polymorphous light eruption (PMLE).

Melanotan will likely be administered by a user-friendly and biodegradable sustained-release implant, administered by injection. Transdermal formulations, such as a lotion, spray or patch are also being developed.

The global dermatology market is estimated at US$2.5bn and the solarium market is in excess of US$5bn in the US alone.

**-End-**

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Thursday 1 July 2004

Company Announcement

# EpiTan completes Level One ADR program

For more information contact:
Iain Kirkwood, Chief Administrative Officer, EpiTan Limited, Tel: +61 3 9662 4688
Davina Bridgeman, Investor Relations & Marketing, EpiTan Limited, Tel: +61 3 9662 4688
Jane Cotter, Oxygen Financial Public Relations, Tel: +61 43877 5997
BNY ADR shareholder queries: Tel: 18882692377 (within U.S.) Tel: 16103827836 (outside U.S)
mail@epitan.com.au
www.epitan.com.au

Melbourne, Australia

EpiTan Limited (ASX: EPT) today announced the establishment of a Level One American Depositary Receipt (ADR) program being declared effective by the US Securities and Exchange Commission (SEC). The Bank of New York was appointed as the depositary bank for the ADR program.

EpiTan Executive Chairman and CEO, Dr Wayne Millen, said the ADR program would give EpiTan access to the important US capital markets and will assist in the development of its leading drug candidate Melanotan® which has significant international potential. He said EpiTan receives a substantial number of investor enquiries from the US and European markets.

The code for the EpiTan ADR is EPTNY and its CUSIP number is 29427H205. Each EpiTan ADR represents 10 ordinary shares of EpiTan as traded on the Australian Stock Exchange (ASX). Trading activity is available on the Bloomberg website: www.bloomberg.com

EpiTan's shares are currently priced at A$ 0.92 (US$ 0.64). The company has 114.3 million shares on issue with a market capitalisation of A$ 105 million (US$ 74 million).

**About ADRs**

ADRs are commonly used to facilitate US investors investing in foreign companies not listed in the USA. An ADR is created when a broker purchases the company's shares on the home stock market and delivers those to the depositary's local custodian bank, which then instructs the depositary bank, The Bank of New York, to issue Depositary Receipts. Depositary Receipts may trade freely, just like any other security, in the over-the-counter (OTC) market.

The company's Level One Depositary Receipts are traded in the US OTC market. The company does not have to comply with US Generally Accepted Accounting Principles (GAAP) or full SEC disclosure. Essentially a sponsored Level One Depositary

Receipts program allows companies to enjoy the benefits of a publicly traded security in the US without changing their current reporting process.

US brokers may deal either directly in EpiTan shares or in ADRs. Some US investors, particularly certain domestic mutual funds, are constrained from investing directly in foreign securities and ADRs provide the opportunity to invest in ASX listed EpiTan.

For those investors who currently own EpiTan shares in an un-sponsored OTC market and who wish to convert their shares to ADRs, please contact your broker.

**About EpiTan**
Melbourne-based biotechnology company EpiTan Limited has the worldwide rights to develop Melanotan® which stimulates the body to make melanin. Melanin is known to protect the body from skin damage as a result of sunburn, a known prime cause of skin cancer. Simply, Melanotan induces a protective tan without exposure to harmful levels of UV radiation.

EpiTan has completed a Phase IIb clinical trial which demonstrated that Melanotan increases melanin content in the skin by up to 100% and reduces sunburn injury by up to 50% in fair-skinned volunteers, representing a significant breakthrough for people most at risk of sunburn injury and skin cancer. Melanotan will shortly undergo clinical studies to assess its potential as a therapy for UV-associated skin disorders such as polymorphous light eruption (PMLE).

Melanotan will likely be administered by a user-friendly and biodegradable sustained-release implant, administered by injection. Transdermal formulations, such as a lotion, spray or patch are also being developed.

The global dermatology market is estimated at US$ 2.5 billion and the solarium market is worth in excess of US$ 5 billion in the US alone.

Dr Perry Robins, Head of Dermatology at New York University Medical Centre and Medical Advisory Consultant to the company, said "I believe the Melanotan technology will save lives. Results of the recent Phase II clinical trial clearly demonstrated that increased levels of melanin protect skin from UV damage. The ability to increase the levels of melanin in the skin safely, combined with sunscreen use will provide individuals with greater protection from the damaging effects of UV radiation."

**-End-**

FILE NO. 82-34790

epitan



28 June 2004

Company Announcements
Australian Stock Exchange Limited
500 Collins Street
MELBOURNE VIC 3000

Dear Sirs

**Change of Director's Interests - Dr W Millen (Weighton Pty Ltd)**

EpiTan Limited lodges on behalf of its executive chairman, Dr W Millen, an Appendix 3Y and Form 604 detailing the recent changes in the shareholding of Weighton Pty Ltd, the company associated with Dr Millen.

Yours faithfully

Iain Kirkwood
Chief Administrative Officer
**EPITAN LIMITED**

**EpiTan Limited** A.B.N. 88 089 644 119
Level 10, 52 Collins Street, Melbourne Victoria Australia 3000
Tel: +613 9662 4688 Fax: +613 9662 4788
www.epitan.com.au

*Rule 3.19A.2*

# Appendix 3Y

## Change of Director's Interest Notice

*Information or documents not available now must be given to ASX as soon as available. Information and documents given to ASX become ASX's property and may be made public.*

Introduced 30/9/2001.

| | |
|---|---|
| **Name of entity** | **EPITAN LIMITED** |
| **ABN** | **88 089 644 119** |

We (the entity) give ASX the following information under listing rule 3.19A.2 and as agent for the director for the purposes of section 205G of the Corporations Act.

| | |
|---|---|
| **Name of Director** | Wayne Millen |
| **Date of last notice** | 10 May 2004 |

**Part 1 - Change of director's relevant interests in securities**
*In the case of a trust, this includes interests in the trust made available by the responsible entity of the trust*

Note: In the case of a company, interests which come within paragraph (i) of the definition of "notifiable interest of a director" should be disclosed in this part.

| | |
|---|---|
| **Direct or indirect interest** | Direct 10,000<br>Indirect 17,866,375 |
| **Nature of indirect interest (including registered holder)**<br>Note: Provide details of the circumstances giving rise to the relevant interest. | Weighton Pty Ltd (trustee of Millen Family Trust) |
| **Date of change** | 28 June 2004 |
| **No. of securities held prior to change** | 18,876,375 |
| **Class** | Ordinary Shares Fully Paid ("EPT") |
| **Number acquired** | Nil |
| **Number disposed** | 150,000 |
| **Value/Consideration**<br>Note: If consideration is non-cash, provide details and estimated valuation | $142,101.72 |
| **No. of securities held after change** | 17,726,375 |

+ See chapter 19 for defined terms.

**Appendix 3Y**
**Change of Director's Interest Notice**

| | |
|---|---|
| **Nature of change**<br>Example: on-market trade, off-market trade, exercise of options, issue of securities under dividend reinvestment plan, participation in buy-back | On market trade – 150,000 |

## Part 2 – Change of director's interests in contracts

Note: In the case of a company, interests which come within paragraph (ii) of the definition of "notifiable interest of a director" should be disclosed in this part.

| | |
|---|---|
| **Detail of contract** | - |
| **Nature of interest** | - |
| **Name of registered holder (if issued securities)** | - |
| **Date of change** | - |
| **No. and class of securities to which interest related prior to change**<br>Note: Details are only required for a contract in relation to which the interest has changed | - |
| **Interest acquired** | - |
| **Interest disposed** | - |
| **Value/Consideration**<br>Note: If consideration is non-cash, provide details and an estimated valuation | - |
| **Interest after change** | - |

+ See chapter 19 for defined terms.

# Form 604

**Corporations Act 2001**
**Section 671B**

## Notice of change of interests of substantial holder

To Company Name/Scheme: Epitan Limited

**ACN/ARSN**: 089 644 119

**1. Details of substantial holder (1)**

Name: Dr Wayne Millen and Weighton Pty Ltd (ACN 008 945 604)

ACN/ARSN (if applicable):

There was a change in the interests of the substantial holder on: 10 May 2004

The previous notice was given to the company on: 20 February 2001

The previous notice was dated: 20 February 2001

**2. Previous and present voting power**

The total number of votes attached to all the voting shares in the company or voting interests in the scheme that the substantial holder or an associate (2) had a relevant interest (3) in when last required, and when now required, to give a substantial holding notice to the company or scheme, are as follows:

| Class of securities (4) | Previous notice | | Present notice | |
|---|---|---|---|---|
| | Person's votes | Voting power (5) | Person's votes | Voting power (5) |
| Ordinary shares | 21,609,503 | 25.0% | 17,876,375 | 15.78% |

**3. Changes in relevant interests**

Particulars of each change in, or change in the nature of, a relevant interest of the substantial holder or an associate in voting securities of the company or scheme, since the substantial holder was last required to give a substantial holding notice to the company or scheme are as follows:

| Date of change | Person whose relevant interest changed | Nature of change (6) | Consideration given in relation to change (7) | Class and number of securities affected | Person's votes affected |
|---|---|---|---|---|---|
| May 2001-June 2002** | Weighton Pty Ltd** | Transfer of Legal and beneficial ownership | Nil** | 1,943,359 ordinary shares** | 1,943,359 votes** |
| 22 December 2003** | Weighton Pty Ltd** | Transfer of Legal and beneficial ownership | $0.311 per share** | 1,398,269 ordinary shares** | 1,398,269 votes** |
| 24 December 2003** | Weighton Pty Ltd** | Transfer of Legal and beneficial ownership | $0.085 per share** | 241,500ordinary shares** | 241,500 votes** |
| 3 May 2004 | Weighton Pty Ltd | Transfer of Legal and beneficial ownership | $0.91 per share | 50,000 ordinary shares | 50,000 votes |
| 5 May 2004 | Weighton Pty Ltd | Transfer of Legal and beneficial ownership | $0.91 per share | 50,000 ordinary shares | 50,000 votes |
| 10 May 2004 | Weighton Pty Ltd | Transfer of Legal and beneficial ownership | $0.99 per share | 50,000 ordinary shares | 50,000 votes |
| ** These changes have previously been notified by Dr Millen and Weighton Pty Ltd in Appendix 3Y notices lodged with ASX. | | | | 3,733,128 ordinary shares | 3,733,128 votes |

**4. Present relevant interests**

Particulars of each relevant interest of the substantial holder in voting securities after the change are as follows:

| Holder of relevant interest | Registered holder of securities | Person entitled to be registered as holder (8) | Nature of relevant interest (6) | Class and number of securities | Person's votes |
|---|---|---|---|---|---|
| Dr W Millen | Weighton Pty Ltd | N/A | Dr Millen is a director and controlling shareholder of entity holding the shares | 17,866,375 | 15.77% |
| | Dr W Millen | N/A | Legal & beneficial holder | 10,000 | 0.01% |
| | | | | | |
| Weighton Pty Ltd | Weighton Pty Ltd | N/A | Legal & beneficial holder | 17,866,375 | 15.77% |

**5. Changes in association**

The persons who have become associates (2) of, ceased to be associates of, or have changed the nature of their association (9) with, the substantial holder in relation to voting interests in the company or scheme are as follows:

| Name and ACN/ARSN (if applicable) | Nature of association |
|---|---|
| N/A | N/A |

**6. Addresses**

The addresses of persons named in this form are as follows:

| Name | Address |
|---|---|
| Weighton Pty Ltd | 1/125 Domain Road, South Yarra, Vic, 3141 |
| Dr W Millen | 1/125 Domain Road, South Yarra, Vic, 3141 |

7. Composite Notice:

This notice is given on behalf of both Dr W Millen and Weighton Pty Ltd, an entity controlled by Dr Millen. The notice is signed by Dr Millen in his personal capacity and as a director of Weighton Pty Ltd. Both Dr Millen and Weighton Pty Ltd have a total voting interest in EpiTan Limited of 15.78%.

## Signature

| | | | |
|---|---|---|---|
| print name | Dr Wayne Millen | capacity | Director |
| **sign here** | | date | 10 May 2004 |

**DIRECTIONS**

(1) If there are a number of substantial holders with similar or related relevant interests (eg. a corporation and its related corporations, or the manager and trustee of an equity trust), the names could be included in an annexure to the form. If the relevant interests of a group of persons are essentially similar, they may be referred to throughout the form as a specifically named group if the membership of each group, with the names and addresses of members is clearly set out in paragraph 6 of the form.

(2) See the definition of "associate" in section 9 of the Corporations Act 2001.

(3) See the definition of "relevant interest" in sections 608 and 671B(7) of the Corporations Act 2001.

(4) The voting shares of a company constitute one class unless divided into separate classes.

(5) The person's votes divided by the total votes in the body corporate or scheme multiplied by 100.

(6) Include details of:

(a) any relevant agreement or other circumstances because of which the change in relevant interest occurred. If subsection 671B(4) applies, a copy of any document setting out the terms of any relevant agreement, and a statement by the person giving full and accurate details of any contract, scheme or arrangement, must accompany this form, together with a written statement certifying this contract, scheme or arrangement; and

(b) any qualification of the power of a person to exercise, control the exercise of, or influence the exercise of, the voting powers or disposal of the securities to which the relevant interest relates (indicating clearly the particular securities to which the qualification applies).

See the definition of "relevant agreement" in section 9 of the Corporations Act 2001.

(7) Details of the consideration must include any and all benefits, money and other, that any person from whom a relevant interest was acquired has, or may, become entitled to receive in relation to that acquisition. Details must be included even if the benefit is conditional on the happening or not of a contingency. Details must be included on any benefit paid on behalf of the substantial holder or its associate in relation to the acquisitions, even if they are not paid directly to the person from whom the relevant interest was acquired.

(8) If the substantial holder is unable to determine the identity of the person (eg. if the relevant interest arises because of an option) write "unknown".

(9) Give details, if appropriate, of the present association and any change in that association since the last substantial holding notice.

**Attention ASX Company Announcements Platform**
**Lodgement of Open Briefing**



epitan

open briefing

corporatefile.com.au

EpiTan Limited
Level 10
52 Collins Street
Melbourne, VIC 3000

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**Date of lodgement:** 16-June-2004

**Title:** Open Briefing. EpiTan. Chairman and CFO on Strategy & Outlook.

**Record of interview:**

**corporatefile.com.au**
EpiTan Limited has recently completed a Phase II trial in relation to the drug Melanotan. EpiTan's market capitalization is currently $99.4 million based on the current share price of $0.87, having traded in a range of $0.66 to $1.02 this calendar year. What is Melanotan and what are its applications?

**Chairman Dr. Wayne Millen**
Melanotan is a more potent synthetic copy of α-*MSH* ("Alpha-Melanocyte Stimulating Hormone"), a naturally occurring peptide hormone which is produced in the body. Melanotan induces a tanning of the skin through a naturally-occurring chemical process called *melanogenesis*, in which the body produces the pigment known as *melanin*. Melanotan provides a natural protective tan to the body. Our primary indication for Melanotan relates to the prevention of sunburn injury, but there is a huge potential application relating to cosmetic tanning.

**corporatefile.com.au**
What are Melanotan's most prospective markets, assuming successful completion of Phase III trials?

**Chairman Dr. Wayne Millen**
We have identified two key markets for Melanotan, the dermatology and the cosmetic markets.

The first most prospective market is dermatology, in which Melanotan would serve as a drug to prevent or reduce sunburn injury. This would most benefit

fair-skinned individuals who are most at risk of sunburn injury. We are also undertaking clinical trials with regard to the potential for Melanotan to treat UV-associated skin disorders, such as Polymorphous Light Eruption (PMLE), a disorder which affects up to 20 percent of Swedes for example and between 10 to 20 percent of the UK and US populations.

The second most prospective market would be the cosmetic market, specifically in the area of tanning. In many parts of the world, a tan is considered fashionable and many people visit solariums or use fake tanning products. Melanotan has the potential to induce an effective natural tan without the need for exposure to harmful levels of UV radiation which can lead to sunburn injury. Sunburn injury is a known key precursor to skin cancer

**corporatefile.com.au**
Could you give an indication as to the potential size of the market for Melanotan?

**Chairman Dr. Wayne Millen**
To give an idea of the size of these prospective markets, the global dermatology market is estimated to be US$2.5 billion per annum.

The global market for treatment of UV-associated skin diseases and disorders is estimated to be US$1 billion per annum.

The cosmetic market in the area of tanning by means of solariums is estimated to be worth US$5 billion per annum in the US alone. It is estimated that some 1 million Americans visit a solarium every day and about 28 million Americans visit solariums in a course of a year. In Europe, there are over 50,000 solariums. In Germany alone there are 25,000 with an annual turnover of US$1.5 billion.

**corporatefile.com.au**
You have been exploring alternative forms of delivery mechanism. Which have the best potential and what are their advantages and disadvantages?

**Chairman Dr. Wayne Millen**
We have been investigating three possible delivery mechanisms for Melanotan. The first is the subcutaneous injection, the second is the transdermal formulation in the form of a lotion and the third is an oral formulation in the form of a tablet.

Melanotan was originally developed in a formulation which was to be administered through an aqueous injection. The disadvantage was that an individual would need ten daily injections in order to get an effective Melanotan dose.

The formulation with the greatest potential for commercialisation and the focus of our clinical trials is the subcutaneous injection, which is a sustained release injectable implant. That is the formulation which our clinical trials to date have proven is safe and most effective.

In association with the Southern Research Institute, Alabama, we have developed a solid sustained release implant which requires a single injection, a

significant advantage over the earlier acquaeous formulation. The sustained release implant can be injected via the same sized needle as used for a blood transfusion or IV drip.

We are currently working on a number of transdermal formulations, in the form of a lotion, spray or patch. The advantage of a transdermal formulation is that it is more user-friendly than an injection. A transdermal application will be regarded as especially advantageous in the paediatric field. Any transdermal lotion formulation is likely to enter the market after the sustained release implant.

With respect to the oral formulation, the gut is very acidic and trying to achieve the right dose for efficacy through the stomach is a technical challenge. One must remember that even given the size of the market, an oral delivery mechanism for insulin has not yet been developed.

**corporatefile.com.au**
What collaborative research partnerships have you engaged in for the advancement of Melanotan?

**Chairman Dr. Wayne Millen**
We currently have collaborative research partnerships in Australia, UK and US.

At the laboratory research level in Australia, our collaborative research studies involve Monash University in Melbourne and the Institute of Medical and Veterinary Science (IMVS) in Adelaide. In the US, we are working with the Southern Research Institute of Birmingham in Alabama. In the UK, we are working with pSiMedica which is a subsidiary of pSivida, a listed company based in Western Australia, who are working on a proof of concept study for a sustained release porous silicon liquid injection.

We are also developing topical lotion formulations in conjunction with US Company CollaGenex and Thomas Sköld from Sweden as well as Transdermal Technologies Inc. of Florida.

**corporatefile.com.au**
When compared with painless popular tanning methods such as sun beds or spray-on tanning products, what are the competitive advantages of the sustained release Melanotan implant and how long does the effectiveness of this implant last?

**Chairman Dr. Wayne Millen**
The key advantage of Melanotan is that it induces a tan without exposure to harmful levels of UV which causes sunburn injury, a key precursor to skin cancer. By taking Melanotan, even particularly fair skinned people will be able to obtain a tan without injurious levels of UV.

Although the duration and the quality of a tan will still vary directly with the amount of UV exposure after receiving Melanotan, there is no need for repeated exposure to harmful levels of UV in order to maintain a natural tan. The key advantage of Melanotan is that the protective *melanin* pigment is

produced, before the person goes out in the sun. Spray on tans only last for 5 to 7 days and offer no protection against UV damage.

A recent study by RAFT in Britain found that most sunscreens fail to stop harmful UVA penetrating the skin which can cause the skin cancer melanoma. In addition, a recent Sydney study has implicated UVA in basal cell damage. Melanin does not discriminate between UVA and UVB rays.

**corporatefile.com.au**
You expect to lodge an Investigational New Drug (IND) application for Melanotan with the US Food and Drug Administration (FDA) in mid-2004. What are the key hurdles involved and what could be the outcome from this application?

**Chairman Dr. Wayne Millen**
The main focus of the FDA and regulators in other parts of the world are safety and the risk-benefit ratio. Secondly, the regulators will focus on a measurable clinical endpoint of a drug. Our particular IND application will relate to our sustained release implant. A successful outcome of our IND application with the FDA is the go ahead to start clinical trials in the US.

**corporatefile.com.au**
What are the likely commencement and end dates for Phase III and what specific objectives and countries will you focus on during the Phase III clinical trials?

**Chairman Dr. Wayne Millen**
Our Phase III clinical trials will focus on sunburn injury and PMLE. We expect to start Phase III trials towards the end of 2004.

Our ultimate objectives are to complete all necessary clinical trials and obtain approval from the FDA and the European Medicines Evaluation Agency (EMEA) in order to market and distribute Melanotan worldwide. We aim to submit a Clinical Trial Exemption (CTA) application to the EMEA in the third quarter of this year and progress to Phase III clinical trials in US, UK, Australia, New Zealand and Europe (most likely in Germany and Sweden).

**corporatefile.com.au**
What are the funding requirements for Phase III and what funding options do you consider viable?

**CFO Iain Kirkwood**
We estimate Phase III clinical trials to require approximately US$20 million. Funding options that we consider viable include securing a larger pharmaceutical company which would collaborate with us in a joint venture and assist us in the funding of the Phase III clinical trials as well as the eventual marketing and distribution of Melanotan. Our partnering talks are progressing well and we will continue to investigate the best outcome for EpiTan's shareholders.

**corporatefile.com.au**
The Australian financial community considers engagement of a suitable partner to help commercialise Melanotan is crucial to the company's progress. What

do you expect any partner to bring to the table? What type of partnership do you envisage? What geographic areas would you be targeting?

**CFO Iain Kirkwood**
Firstly, a suitable partner will bring funding. Secondly, a suitable partner will reduce the risk of bringing Melanotan to market as they would have the necessary technical, regulatory, marketing and distribution expertise. Thirdly, the partner would enhance the credibility of both our Phase III clinical trials and the drug itself.

Ideally, the partner would be US-centric or Euro-centric and have global distribution power. We have already established very strong relationships with drug manufacturing companies in Europe and America and intend to maintain control of this aspect. In terms of our home market, we aim to manage Australia and New Zealand ourselves.

**corporatefile.com.au**
How might the revenue flows be structured in any collaboration?

**CFO Iain Kirkwood**
Partnership deals with larger pharmaceutical companies can for example include an initial sign-on fee, several milestone payments, co-promotion/co-marketing arrangements and a royalty fee. Milestone payments could be made, for example, relating to FDA approvals, the outcome of Phase III clinical trials, and, finally, the FDA approval for marketing the new drug. These arrangements would be established with respect to specific jurisdictions and typically EpiTan expects to get a double digit royalty fee on the overall sales of the drug. A higher royalty rate for sales above a certain level can also be negotiated. In addition, the joint venture partner would reimburse us for all future clinical trial costs.

**corporatefile.com.au**
What have you identified as the key challenges in taking Melanotan through to commercialisation?

**Chairman Dr. Wayne Millen**
A key challenge in taking any drug through to commercialisation is being able to meet the safety and risk benefit ratio standards required by the relevant regulatory authorities because this is their prime focus. The other key challenges are time and money. On average, drugs take 12 to 15 years to go from test tube to prescription pad and the Melanotan project has already taken some 13 years since the first clinical trial information was published.

**corporatefile.com.au**
What is your patent position? Are you expecting new patents to emerge? When will your worldwide exclusive rights to develop Melanotan lapse?

**Chairman Dr. Wayne Millen**
Our patent position is very strong and grants us worldwide exclusive rights to develop Melanotan. We expect to be the first company to licence this new drug to the US and under the Hatch Waxman Act we are automatically granted five years of marketing exclusivity. This means that the US FDA would not review an application for this drug for the same application for a five-year

period. Also any new indications licensed for this drug are granted a further three years of marketing exclusivity. In Europe and Australia there are similar provisions for marketing exclusivity, which cover between 8 and 11 years.

The emergence of any new patents would reinforce and possibly extend our marketing exclusivity, making it very difficult for other companies to compete with us We expect new IP to emerge from discoveries made during our recent as well as future clinical trials and research programmes.

**corporatefile.com.au**
Which companies and what products do you regard as your closest competitors in each of the target markets and specific countries you expect to market Melanotan?

**Chairman Dr. Wayne Millen**
To the best of our knowledge, no other prescription drug similar to Melanotan either exists in the market or is undergoing clinical trials, and there are no products which offer sunburn injury protection other than sunscreens. We have already successfully proven in our clinical trials to date that Melanotan induced an increase in *melanin* density of up to 100% in some fair-skinned volunteers with a subsequent 50% reduction in sunburn injury.

We are confident that we will be the first to commercialise Melanotan in a few years time and would enjoy the monopoly position in the world's largest pharmaceutical markets for several years as guaranteed by our exclusivity period and future patents. We expect our key markets to be in the US, Canada, Europe, Australia and New Zealand.

**corporatefile.com.au**
Thank you Wayne and Iain.

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For more information about EpiTan Limited, view www.epitan.com.au.

**5. Changes in association**

The persons who have become associates (2) of, ceased to be associates of, or have changed the nature of their association (9) with, the substantial holder in relation to voting interests in the company or scheme are as follows:

| Name and ACN/ARSN (if applicable) | Nature of association |
|---|---|
| N/A | N/A |
| | |

**6. Addresses**

The addresses of persons named in this form are as follows:

| Name | Address |
|---|---|
| Weighton Pty Ltd | 1/125 Domain Road, South Yarra, VIC, 3141 |
| Dr W. Millen | 1/125 Domain Road, South Yarra, VIC, 3141 |

**7. Composite Notice**

This notice is given on behalf of both Dr Wayne Millen and Weighton Pty Ltd, an entity controlled by Dr Wayne Millen. The notice is signed by Dr Millen in his personal capacity and as a director of Weighton Pty Ltd. Both Dr Millen and Weighton Pty Ltd have a total voting interest in EpiTan Limited of 15.51%.

## Signature

| | | | |
|---|---|---|---|
| print name | Dr Wayne Millen | capacity | Director |
| **sign here** | Wayne A. Millen | date | 28 June 2004 |

**DIRECTIONS**

(1) If there are a number of substantial holders with similar or related relevant interests (eg. a corporation and its related corporations, or the manager and trustee of an equity trust), the names could be included in an annexure to the form. If the relevant interests of a group of persons are essentially similar, they may be referred to throughout the form as a specifically named group if the membership of each group, with the names and addresses of members is clearly set out in paragraph 6 of the form.

(2) See the definition of "associate" in section 9 of the Corporations Act 2001.

(3) See the definition of "relevant interest" in sections 608 and 671B(7) of the Corporations Act 2001.

(4) The voting shares of a company constitute one class unless divided into separate classes.

(5) The person's votes divided by the total votes in the body corporate or scheme multiplied by 100.

(6) Include details of:

(a) any relevant agreement or other circumstances because of which the change in relevant interest occurred. If subsection 671B(4) applies, a copy of any document setting out the terms of any relevant agreement, and a statement by the person giving full and accurate details of any contract, scheme or arrangement, must accompany this form, together with a written statement certifying this contract, scheme or arrangement; and

(b) any qualification of the power of a person to exercise, control the exercise of, or influence the exercise of, the voting powers or disposal of the securities to which the relevant interest relates (indicating clearly the particular securities to which the qualification applies).

See the definition of "relevant agreement" in section 9 of the Corporations Act 2001.

(7) Details of the consideration must include any and all benefits, money and other, that any person from whom a relevant interest was acquired has, or may, become entitled to receive in relation to that acquisition. Details must be included even if the benefit is conditional on the happening or not of a contingency. Details must be included on any benefit paid on behalf of the substantial holder or its associate in relation to the acquisitions, even if they are not paid directly to the person from whom the relevant interest was acquired.

(8) If the substantial holder is unable to determine the identity of the person (eg. if the relevant interest arises because of an option) write "unknown".

(9) Give details, if appropriate, of the present association and any change in that association since the last substantial holding notice.

**epitan**

Monday 31 May, 2004

# Company Announcement

## BBY Report Amendment

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For more information contact:
Iain Kirkwood, Chief Administrative Officer, EpiTan Limited, Tel: 03 9662 4688
Davina Bridgeman, Marketing and Investor Relations, EpiTan Limited, Tel: 03 9662 4688
Richard Allen, Monsoon Communications, Tel: 03 9620 3333
mail@epitan.com.au
www.epitan.com.au

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Melbourne, Australia

EpiTan Limited [ASX:EPT] today announced that stockbroker Burdett Buckeridge Young Limited (BBY) has amended its research report, which was issued last week.

BBY's revised report is now available on the EpiTan website www.epitan.com.au.

In the revised report's pricing section, the analyst now says: "BBY believes that Melanotan may provide an annual revenue stream for EpiTan of more than US$ 50 million, assuming the company partners with a large pharmaceutical company and earns a royalty of between 5% and 10% of total sales revenue."

End

*Rule 3.19A.2*

# Appendix 3Y

## Change of Director's Interest Notice

*Information or documents not available now must be given to ASX as soon as available. Information and documents given to ASX become ASX's property and may be made public.*

Introduced 30/9/2001.

| | |
|---|---|
| **Name of entity** | **EPITAN LIMITED** |
| **ABN** | **88 089 644 119** |

We (the entity) give ASX the following information under listing rule 3.19A.2 and as agent for the director for the purposes of section 205G of the Corporations Act.

| | |
|---|---|
| **Name of Director** | Terry Winters |
| **Date of last notice** | 22 December 2003 |

**Part 1 - Change of director's relevant interests in securities**
*In the case of a trust, this includes interests in the trust made available by the responsible entity of the trust*

Note: In the case of a company, interests which come within paragraph (i) of the definition of "notifiable interest of a director" should be disclosed in this part.

| | |
|---|---|
| **Direct or indirect interest** | Direct |
| **Nature of indirect interest (including registered holder)**<br>Note: Provide details of the circumstances giving rise to the relevant interest. | N/A |
| **Date of change** | 31 May 2004 |
| **No. of securities held prior to change** | 150,000 |
| **Class** | Fully paid ordinary shares |
| **Number acquired** | 750,000 |
| **Number disposed** | Nil |
| **Value/Consideration**<br>Note: If consideration is non-cash, provide details and estimated valuation | $225,000.00 |
| **No. of securities held after change** | 900,000 |

+ See chapter 19 for defined terms.

**Appendix 3Y**
**Change of Director's Interest Notice**

| | |
|---|---|
| **Nature of change**<br>Example: on-market trade, off-market trade, exercise of options, issue of securities under dividend reinvestment plan, participation in buy-back | Exercise of 750,000 (unquoted) directors' options at $0.30 per share |

## Part 2 – Change of director's interests in contracts

Note: In the case of a company, interests which come within paragraph (ii) of the definition of "notifiable interest of a director" should be disclosed in this part.

| | |
|---|---|
| **Detail of contract** | - |
| **Nature of interest** | - |
| **Name of registered holder (if issued securities)** | - |
| **Date of change** | - |
| **No. and class of securities to which interest related prior to change**<br>Note: Details are only required for a contract in relation to which the interest has changed | - |
| **Interest acquired** | - |
| **Interest disposed** | - |
| **Value/Consideration**<br>Note: If consideration is non-cash, provide details and an estimated valuation | - |
| **Interest after change** | - |

+ See chapter 19 for defined terms.

*Rule 2.7, 3.10.3, 3.10.4, 3.10.5*

# Appendix 3B

## New issue announcement, application for quotation of additional securities and agreement

*Information or documents not available now must be given to ASX as soon as available. Information and documents given to ASX become ASX's property and may be made public.*

Introduced 1/7/96. Origin: Appendix 5. Amended 1/7/98, 1/9/99, 1/7/2000, 30/9/2001, 11/3/2002, 1/1/2003.

Name of entity

EPITAN LIMITED

ABN

88 089 644 119

We (the entity) give ASX the following information.

## Part 1 - All issues

*You must complete the relevant sections (attach sheets if there is not enough space).*

| | | |
|---|---|---|
| 1 | +Class of +securities issued or to be issued | Ordinary Shares |
| 2 | Number of +securities issued or to be issued (if known) or maximum number which may be issued | 1,000,000 ordinary shares |
| 3 | Principal terms of the +securities (eg, if options, exercise price and expiry date; if partly paid +securities, the amount outstanding and due dates for payment; if +convertible securities, the conversion price and dates for conversion) | Exercise of 750,000 unquoted (directors) options at 30 cents each<br>Exercise of 250,000 unquoted (incentive) options at 10 cents each |

+ See chapter 19 for defined terms.

**Appendix 3B**
**New issue announcement**

| | | |
|---|---|---|
| 4 | Do the +securities rank equally in all respects from the date of allotment with an existing +class of quoted +securities?<br><br>If the additional securities do not rank equally, please state:<br>• the date from which they do<br>• the extent to which they participate for the next dividend, (in the case of a trust, distribution) or interest payment<br>• the extent to which they do not rank equally, other than in relation to the next dividend, distribution or interest payment | Yes |
| 5 | Issue price or consideration | Total $250,000.00 |
| 6 | Purpose of the issue<br>(If issued as consideration for the acquisition of assets, clearly identify those assets) | Exercise of 750,000 unquoted (directors) options<br>Exercise of 250,000 unquoted (incentive) options |
| 7 | Dates of entering +securities into uncertificated holdings or despatch of certificates | 31 May 2004 |
| 8 | Number and +class of all +securities quoted on ASX (*including* the securities in clause 2 if applicable) | Number: 114,303,239 EPT<br>+Class: ordinary |

+ See chapter 19 for defined terms.

| | | | |
|---|---|---|---|
| 9 | Number and +class of all +securities not quoted on ASX (*including* the securities in clause 2 if applicable) | Number<br>5,762,402 | +Class<br>EpiTan Incentive Option Plan |
| 10 | Dividend policy (in the case of a trust, distribution policy) on the increased capital (interests) | Ordinary shares ranking equally with existing ordinary shares | |

## Part 2 - Bonus issue or pro rata issue

| | | |
|---|---|---|
| 11 | Is security holder approval required? | |
| 12 | Is the issue renounceable or non-renounceable? | |
| 13 | Ratio in which the +securities will be offered | |
| 14 | +Class of +securities to which the offer relates | |
| 15 | +Record date to determine entitlements | |
| 16 | Will holdings on different registers (or subregisters) be aggregated for calculating entitlements? | |
| 17 | Policy for deciding entitlements in relation to fractions | |
| 18 | Names of countries in which the entity has +security holders who will not be sent new issue documents<br>Note: Security holders must be told how their entitlements are to be dealt with.<br>Cross reference: rule 7.7. | |
| 19 | Closing date for receipt of acceptances or renunciations | |

+ See chapter 19 for defined terms.

**Appendix 3B**
**New issue announcement**

| | | |
|---|---|---|
| 20 | Names of any underwriters | |
| 21 | Amount of any underwriting fee or commission | |
| 22 | Names of any brokers to the issue | |
| 23 | Fee or commission payable to the broker to the issue | |
| 24 | Amount of any handling fee payable to brokers who lodge acceptances or renunciations on behalf of +security holders | |
| 25 | If the issue is contingent on +security holders' approval, the date of the meeting | |
| 26 | Date entitlement and acceptance form and prospectus or Product Disclosure Statement will be sent to persons entitled | |
| 27 | If the entity has issued options, and the terms entitle option holders to participate on exercise, the date on which notices will be sent to option holders | |
| 28 | Date rights trading will begin (if applicable) | |
| 29 | Date rights trading will end (if applicable) | |
| 30 | How do +security holders sell their entitlements *in full* through a broker? | |
| 31 | How do +security holders sell *part* of their entitlements through a broker and accept for the balance? | |

+ See chapter 19 for defined terms.

| | | |
|---|---|---|
| 32 | How do +security holders dispose of their entitlements (except by sale through a broker)? | |
| 33 | +Despatch date | |

# Part 3 - Quotation of securities

*You need only complete this section if you are applying for quotation of securities*

34 Type of securities
(*tick one*)

(a) ☒ Securities described in Part 1

(b) ☐ All other securities

Example: restricted securities at the end of the escrowed period, partly paid securities that become fully paid, employee incentive share securities when restriction ends, securities issued on expiry or conversion of convertible securities

## Entities that have ticked box 34(a)

### Additional securities forming a new class of securities

*Tick to indicate you are providing the information or documents*

35 ☐ If the +securities are +equity securities, the names of the 20 largest holders of the additional +securities, and the number and percentage of additional +securities held by those holders

36 ☐ If the +securities are +equity securities, a distribution schedule of the additional +securities setting out the number of holders in the categories
1 - 1,000
1,001 - 5,000
5,001 - 10,000
10,001 - 100,000
100,001 and over

37 ☐ A copy of any trust deed for the additional +securities

+ See chapter 19 for defined terms.

## Entities that have ticked box 34(b)

| | | |
|---|---|---|
| 38 | Number of securities for which +quotation is sought | |
| 39 | Class of +securities for which quotation is sought | |
| 40 | Do the +securities rank equally in all respects from the date of allotment with an existing +class of quoted +securities?<br><br>If the additional securities do not rank equally, please state:<br>• the date from which they do<br>• the extent to which they participate for the next dividend, (in the case of a trust, distribution) or interest payment<br>• the extent to which they do not rank equally, other than in relation to the next dividend, distribution or interest payment | |
| 41 | Reason for request for quotation now<br><br>Example: In the case of restricted securities, end of restriction period<br><br>(if issued upon conversion of another security, clearly identify that other security) | |

| 42 | Number and +class of all +securities quoted on ASX (*including* the securities in clause 38) | Number | +Class |
|---|---|---|---|
| | | | |

+ See chapter 19 for defined terms.

**Quotation agreement**

1 +Quotation of our additional +securities is in ASX's absolute discretion. ASX may quote the +securities on any conditions it decides.

2 We warrant the following to ASX.

- The issue of the +securities to be quoted complies with the law and is not for an illegal purpose.
- There is no reason why those +securities should not be granted +quotation.
- An offer of the +securities for sale within 12 months after their issue will not require disclosure under section 707(3) or section 1012C(6) of the Corporations Act.

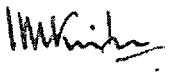
  Note: An entity may need to obtain appropriate warranties from subscribers for the securities in order to be able to give this warranty

- Section 724 or section 1016E of the Corporations Act does not apply to any applications received by us in relation to any +securities to be quoted and that no-one has any right to return any +securities to be quoted under sections 737, 738 or 1016F of the Corporations Act at the time that we request that the +securities be quoted.
- We warrant that if confirmation is required under section 1017F of the Corporations Act in relation to the +securities to be quoted, it has been provided at the time that we request that the +securities be quoted.
- If we are a trust, we warrant that no person has the right to return the +securities to be quoted under section 1019B of the Corporations Act at the time that we request that the +securities be quoted.

+ See chapter 19 for defined terms.

3 We will indemnify ASX to the fullest extent permitted by law in respect of any claim, action or expense arising from or connected with any breach of the warranties in this agreement.

4 We give ASX the information and documents required by this form. If any information or document not available now, will give it to ASX before +quotation of the +securities begins. We acknowledge that ASX is relying on the information and documents. We warrant that they are (will be) true and complete.

Sign here:  Date: 31 May 2004

(~~Director~~/Company secretary)

Print name: I.M. Kirkwood

== == == == ==

+ See chapter 19 for defined terms.

epitan

6 May 2004

## Company Announcement

## EpiTan appoints The Bank of New York to establish a US Level One ADR programme

For more information contact:
Iain Kirkwood, Chief Financial Officer, EpiTan Limited, Tel: 03 9662 4688
Davina Bridgeman, IR and Marketing, EpiTan Limited, Tel: 03 9662 4688
Richard Allen, Monsoon Communications, Tel: 03 9620 3333
mail@epitan.com.au
www.epitan.com.au

Melbourne, Australia

Drug-development company EpiTan Limited (ASX:EPT) today announced that it had entered in to an agreement with The Bank of New York to assist in the establishment of a Level One American Depositary Receipt (ADR) programme.

The key objective of establishing this programme is to drive value for investors in the company by:

- improving the liquidity of shares traded by US resident investors currently not sponsored by the company,
- offering access for those investors currently prohibited or limited in owning non-US securities,
- increasing the visibility and profile of EpiTan in the world's largest capital market.

This move is a logical progression in the company's international development as it has previously announced that it will be commencing clinical trials in the US as soon as it has lodged an IND with the Food and Drug Administration in mid 2004.

The company already has a number of US resident shareholders including Melanotan Corporation Inc, a major shareholder with 15.2 million shares (13.4%).

American Depositary Receipts are commonly used to facilitate US investors investing in foreign companies not listed in the USA. An ADR is created when a broker purchases the company's shares on the home stock market and delivers those to the depositary's local custodian bank, which then instructs the depositary bank, The Bank of New York, to issue ADRs. ADRs may trade freely, just like any other security, in the US Over-the-Counter (OTC) market.

**-End-**