epitan

25 February 2004

ASX Release

Half yearly report – 31 December 2003

Commentary and Highlights

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Melbourne, Australia

Australian drug development company EpiTan Limited [ASX:EPT] is pleased to announce its half yearly report for the six months ended 31 December 2003. A financial report and Appendix 4D follow this commentary.

Key points:

- The clinical development of the melanin-producing drug, Melanotan®, continues to be very successful
- Successful discussions with the FDA in a pre-IND meeting in October 2003. Outcomes of this meeting included an indication from the FDA that use of Melanotan as a "prescription sunscreen" would be an appropriate endpoint to follow. EpiTan expects to submit an IND in Q3 2004 to continue the Phase II programme in the USA to validate this endpoint
- The drug completed pivotal Phase IIb clinical trials in November 2003. These trials, which used the daily aqueous injection, conclusively demonstrated that Melanotan consistently elevated skin melanin levels all over the body. This elevated melanin in skin type I/II correlated with a 50% reduction in sunburn injury as well as a significant reduction in damage to DNA in skin cells. <u>This is the first time that a drug has been demonstrated to induce a protective level of melanin in people who normally do not make any significant amounts of melanin.</u> It is also the first time that the protective elements of melanin can be clearly shown in humans by the fact that the level of melanin could be increased in the skin by means other than by damaging the cells with UV radiation
- A more user friendly delivery formulation of Melanotan in the form of a single sustained-release (SR) solid injectable (or implant) was

successfully developed to replace the daily aqueous injections used in all previous trials

- A dose escalation trial began in late November 2003 to determine the optimal dose for the new SR solid injectable. By January 2004 better than expected efficacy had been demonstrated. The first six volunteers, who received the two lowest levels of Melanotan, quickly demonstrated, a substantial increase in melanin levels. After 60 days the volunteers still had a profound natural tan
- $9.1 million additional capital raised during the first half year
- Cash resources totalled $7.6 million at 31 December 2003
- Market capitalisation $74.9 million at 31 December 2003

Outlook

The company is now very well poised to capitalise on the excellent clinical trial progress made during the first half of the financial year. The company's success has continued into 2004 with the better than expected efficacy from the SR solid injectable trial underway in Queensland. This is particularly encouraging because, importantly, the new formulation has been shown to work and the physical size of the SR solid injectable has been reduced significantly to enable easier administration. The focus remains to determine the optimal dose for the SR solid injectable and EpiTan now expects the trials to conclude in the third quarter 2004.

The appointment of the eminent New York-based skin-cancer specialist Professor Perry Robins as a Medical Advisory Consultant will facilitate the expansion of EpiTan's clinical trials into the USA and Europe this year. He is also introducing the company to a select group of large pharmaceutical companies with whom Epitan will be actively discussing partnering arrangements. This is a key corporate objective in 2004 to assist, inter alia, with the funding of Phase III trials.

Considerable interest is now being shown by several large pharmaceutical companies and discussions have opened on a number of fronts.

A clinical trial to determine the prophylactic effect of Melanotan on reducing the clinical symptoms related to Polymorphous Light Eruption ("PMLE") has received ethics committee approval and is scheduled to commence at two sites in Germany in March 2004.

The planned Phase III trials will be the final piece of Melanotan's exhaustive clinical programme. They will be multi-centred and worldwide studies under the auspices of the regulatory authorities of Australia, USA and Europe. It is planned to submit marketing applications for Melanotan in parallel in all of the major world markets.

-End-

Appendix 4D

Half Yearly Report
Half Year Ended 31 December 2003

Name of entity

EPITAN LIMITED

ABN or equivalent company reference

88 089 644 119

Half year ended ('current period')

31 December 2003
(Previous corresponding period: 31 December 2002)

Results for announcement to the market

				$A'000
Revenues from ordinary activities	Up	96%	to	168
Profit (loss) from ordinary activities after tax attributable to members	Down	103%	to	(3,807)
Net profit (loss) for the period attributable to members	Down	103%	to	(3,807)

Dividends (distributions)	Amount per security	Franked amount per security
Final dividend *	*Nil ¢	*Nil ¢
Interim dividend	*Nil ¢	*Nil ¢

EpiTan Limited has not paid any dividends during the 2003 financial year.

Previous corresponding period (30 June 2002)	Nil ¢	Nil ¢
Record date for determining entitlements to the dividend	N/A	N/A

Brief explanation of any of the figures reported above and short details of any bonus or cash issue or other item(s) of importance not previously released to the market:

- Not applicable

Commentary on Results

For commentary on the results of EpiTan Limited refer to the Half-Year Report in conjunction with the details and explanations provided herewith.

Ratios and Other measures

NTA backing	Current period	Previous corresponding period
Net tangible asset backing per ordinary security	6 cents	4 cents

Additional Disclosure

As per ASX listing rule 4.2A.3, for the six month period ending 31 December 2003:

Control gained over entities having material effect

Name of entity (or group of entities)	N/A
Consolidated profit (loss) from ordinary activities and extraordinary items after tax of the controlled entity (or groups of entities) since the date in the current period on which control was +acquired	N/A
Date from which such profit has been calculated	N/A
Profit (loss) from ordinary activities and extraordinary items after tax of the controlled entity 9or group of entities) fro the whole of the previous corresponding period	N/A

Loss of control of entities having material effect

Name of entity (or group of entities)	N/A
Consolidated profit (loss) from ordinary activities and extraordinary items after tax of the controlled entity (or group of entities) for the current period to the date of loss of control	N/A
Date to which the profit (loss) has been calculated	N/A
Consolidated profit (loss) from ordinary activities and extra ordinary items after tax of the controlled entity (or group of entities) while controlled during the whole of the previous corresponding period	N/A

Dividends (in the case of a trust, distributions)

Date the dividend (distribution) is payable	N/A
+Record date determine entitlements to the dividend (distribution) (ie, on the basis of proper instruments of transfer received by 5.00pm if +securities are not +CHESS approved, or security holding balances established by 5.00pm or such later time permitted by SCH business Rules if +securities are +CHESS approved)	N/A
If it is a final dividend, has it been declared?	N/A

Details of aggregate share of profits (losses) of associates and joint venture entities

Group's share of associates' and joint ventures entities':	Current Period $A'000	Previous Corresponding period - $A'000
Profit (loss) from ordinary activities before tax	N/A	N/A
Income tax on ordinary activities	N/A	N/A
Profit (loss) from ordinary activities after tax	N/A	N/A
Extraordinary items net of tax	N/A	N/A
Net profit (loss)	N/A	N/A
Adjustments	N/A	N/A
Share of net profit (loss) of associates and joint venture entities	N/A	N/A

EPITAN LIMITED
A.B.N. 88 089 644 119
AND CONTROLLED ENTITY
FINANCIAL REPORT
HALF YEAR ENDED
31 DECEMBER 2003

EPITAN LIMITED
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EPITAN LIMITED
A.B.N. 88 089 644 119
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DIRECTORS' REPORT

Your directors present their report on the company and its controlled entity for the half year ended 31 December 2003.

DIRECTORS

The names of directors in office at any time during or since the end of the half year are:

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

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

REVIEW AND RESULTS OF OPERATIONS

Highlights for the half year period

- The clinical development of the melanin-producing drug, Melanotan®, continues to be very successful
- Successful discussions with the FDA in a pre-IND meeting in October 2003. Outcomes of this meeting included an indication from the FDA that use of Melanotan as a "prescription sunscreen" would be an appropriate endpoint to follow. EpiTan expects to submit an IND in Q3 2004 to continue the Phase II programme in the USA to validate this endpoint
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EPITAN LIMITED
A.B.N. 88 089 644 119
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DIRECTORS' REPORT (CONTINUED)

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

S.R. MCLIESH
DIRECTOR

W.A. MILLEN
DIRECTOR

Dated this 25th day of February, 2004.

EPITAN LIMITED
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AND CONTROLLED ENTITY

CONDENSED STATEMENT OF FINANCIAL PERFORMANCE

FOR THE HALF YEAR ENDED 31 DECEMBER 2003

		Consolidated	
	Note	**31 December 2003 $**	**31 December 2002 $**
Revenues from ordinary activities	2	168,066	85,617
Total expenses from ordinary activities	2	(3,975,081)	(1,956,553)
Profit(loss) from ordinary activities before related income tax expense		(3,807,015)	(1,870,936)
Income tax expense (benefit) relating to ordinary activities		-	-
Profit(loss) from ordinary activities after related income tax expense		(3,807,015)	(1,870,936)
Net profit(loss)		(3,807,015)	(1,870,936)
Net profit(loss) attributable to members of EpiTan Limited		(3,807,015)	(1,870,936)
Total changes in equity other than those resulting from transactions with owners as owners		(3,807,015)	(1,870,936)
Basic earnings per share - cents per share		(3.6)	(2.1)

EPITAN LIMITED
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CONDENSED STATEMENT OF FINANCIAL POSITION

AS AT 31 DECEMBER 2003

	Consolidated	
	31 December 2003 $	30 June 2003 $
CURRENT ASSETS		
Cash assets	4,568,479	2,611,853
Receivables	10,545	30,832
Investments	2,982,283	-
Other	73,439	105,643
TOTAL CURRENT ASSETS	7,634,746	2,748,328
NON CURRENT ASSETS		
Property, plant and equipment	141,236	147,176
Intangible assets	4,810,252	5,170,662
TOTAL NON CURRENT ASSETS	4,951,488	5,317,838
TOTAL ASSETS	12,586,234	8,066,166
CURRENT LIABILITIES		
Payables	551,506	465,826
Provisions	83,047	69,625
TOTAL CURRENT LIABILITIES	634,553	535,451
TOTAL LIABILITIES	634,553	535,451
NET ASSETS	11,951,681	7,530,715
EQUITY		
Contributed equity	24,808,422	16,580,441
Accumulated losses	(12,856,741)	(9,049,726)
TOTAL EQUITY	11,951,681	7,530,715

EPITAN LIMITED
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CONDENSED STATEMENT OF CASH FLOWS

FOR THE HALF YEAR ENDED 31 DECEMBER 2003

	Consolidated	
	31 December 2003 $	31 December 2002 $
CASH FLOWS FROM OPERATING ACTIVITIES		
Refund from ATO	194,781	25,313
Payments to suppliers and employees	(3,602,344)	(1,533,014)
Interest received	145,274	102,205
Net cash provided by (used in) operating activities	(3,262,289)	(1,405,496)
CASH FLOWS FROM INVESTING ACTIVITIES		
Payments for property, plant and equipment	(13,545)	(57,863)
Payments for trademarks	(10,742)	(3,558)
Payments for patents	(2,496)	-
Payments for investments	(2,982,283)	-
Net cash provided by (used in) investing activities	(3,009,066)	(61,421)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issue of ordinary shares	9,108,237	-
Payment of share issue costs	(880,256)	-
Net cash provided by (used in) financing activities	8,227,981	-
Net increase/(decrease) in cash held	1,956,626	(1,466,917)
Cash at beginning of the year	2,611,853	4,414,100
Cash at end of the year	4,568,479	2,947,183

EPITAN LIMITED
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NOTES TO THE FINANCIAL STATEMENTS

FOR THE HALF YEAR ENDED 31 DECEMBER 2003

1. BASIS OF PREPARATION OF THE HALF YEAR FINANCIAL REPORT

The half-year financial report does not include all notes of the type normally included within the annual financial report and therefore cannot be expected to provide as full an understanding of the financial performance, financial position and financing and investing activities of the consolidated entity as the full financial report.

The half-year financial report should be read in conjunction with the Annual Financial report of EpiTan Limited as at 30 June 2003. It is also recommended that the half-year financial report be considered together with any public announcements made by EpiTan Limited and its controlled entities during the half-year ended 31 December 2003 in accordance with the continuous disclosure obligations arising under the Corporations Act 2001.

(a) Basis of accounting

The half-year financial report is a general purpose financial report that has been prepared in accordance with Accounting Standards, Urgent Issues Group Consensus Views, other authoritative pronouncements of the Australian Accountancy Standards Board and the Corporations Act 2001. The half-year financial report has been prepared on an accruals basis and is based on historical costs and does not take into account changing money values or, except where stated, current valuations of non current assets. Cost is based on the fair values of the consideration given in exchange for assets. The accounting policies applied in this report are consistent with those applied in the 30 June 2003 Annual Financial Report.

For the purpose of preparing the half-year financial report, the half-year has been treated as a discrete reporting period.

EPITAN LIMITED
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NOTES TO THE FINANCIAL STATEMENTS

FOR THE HALF YEAR ENDED 31 DECEMBER 2003

	Consolidated	
	31 December 2003 $	31 December 2002 $
2. PROFIT/(LOSS) FROM ORDINARY ACTIVITIES		
(a) Specific Items		
Profit/(loss) from ordinary activities before income tax expense includes the following revenue and expenses whose disclosure is relevant in explaining the financial performance of the entity.		
(i) Revenues from ordinary activities		
Interest revenue – other persons	168,066	85,617
(ii) Expenses from ordinary activities		
Depreciation	19,485	22,284
Amortisation of sub-licence	373,649	373,649
Research & development costs	880,461	940,372

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NOTES TO THE FINANCIAL STATEMENTS

FOR THE HALF YEAR ENDED 31 DECEMBER 2003

3. DIVIDENDS PAID OR PROVIDED FOR ON ORDINARY SHARES

No dividends have been paid or provided for in either the half year or prior reporting periods.

4. SEGMENT INFORMATION

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

5. CONTINGENT ASSETS AND LIABILITIES

The economic entity has no material contingent assets or liabilities. This is consistent with the last annual reporting date.

EPITAN LIMITED
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DIRECTORS' DECLARATION

In the opinion of the directors:

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

    (a) giving a true and fair view of the company's and the consolidated entity's financial position as at 31 December 2003 and of their performance for the half year ended on that date;
    (b) complying with Accounting Standards and the Corporations Regulations 2001; and

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

This declaration is made in accordance with a resolution of the Board of Directors.

S.R. MCLIESH	W.A.MILLEN
DIRECTOR	DIRECTOR

Dated this 25th day of February, 2004.

William Buck
Business Advisors
Chartered Accountants

INDEPENDENT REVIEW REPORT
TO THE MEMBERS OF EPITAN LIMITED & CONTROLLED ENTITY

Scope

We have reviewed the half year financial report of Epitan Limited & controlled entity for the half year ended 31 December 2003 comprising the Consolidated Statement of Financial Performance, Consolidated Statement of Financial Position, Consolidated Statement of Cash Flows, notes to and forming part of the financial statements and the Directors' Declaration.

The half year financial report includes the financial statements of the consolidated entity comprising the disclosing entity and the entities it controlled at the end of the half-year or from time to time during the half-year. The disclosing entity's directors are responsible for the half year financial report.

We have performed an independent review of the half year financial report in order to state whether, on the basis of procedures described, anything has come to our attention that would indicate that the half year financial report is not presented fairly in accordance with Accounting Standard AASB 1029: Interim Financial Reporting and other mandatory professional reporting requirements in Australia and statutory requirements, so as to present a view which is consistent with our understanding of the consolidated entity's financial position, and performance as represented by the results of its operations and its cash flows, and in order for the disclosing entity to meet its obligations to lodge the financial report with the Australian Securities and Investments Commission.

Our review has been conducted in accordance with Australian Auditing Standards applicable to review engagements. A review is limited primarily to inquiries of the entity's personnel and analytical procedures applied to the financial data. These procedures do not provide all the evidence that would be required in an audit, thus the level of assurance is less than given in an audit. We have not performed an audit and, accordingly, we do not express an audit opinion.

Statement

Based on our review, which is not an audit, we have not become aware of any matter that makes us believe that the half-year financial report, as defined in the scope section of Epitan Limited & controlled entity is not in accordance with:

(a) the Corporations Act 2001, including:

- (i) giving a true and fair view of the consolidated entity's financial position as at 31 December 2003 and of its performance for the half-year ended on that date; and
- (ii) complying with Accounting Standard AASB 1029: Interim Financial Reporting and the Corporations Regulations 2001; and

(b) other mandatory professional reporting requirements in Australia.

William Buck

WILLIAM BUCK
Chartered Accountants

Ken Glynn
Partner

Dated this 25th of February 2004