

**HALF-YEAR REPORT**  
**PEPLIN BIOTECH LIMITED**

**A.B.N. 55 090 819 275**

**31 DECEMBER 2003**

# PEPLIN BIOTECH LIMITED AND CONTROLLED ENTITIES

## DIRECTORS' REPORT

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Your directors present their report on the consolidated entity consisting of Peplin Biotech Limited (Peplin) and the entities it controlled at the end of, or during, the half-year ended 31 December 2003.

### 1. Directors

The following persons were directors of Peplin during the whole of the half-year and up to the date of this report, except as noted:

C Hirst  
GL Redlich (resigned 10 October 2003)  
MDA Aldridge (appointed 10 October 2003)  
JH Aylward  
WK Goss  
JBL Heading  
MR Spooner (appointed 10 February 2004)

### 2. Review of Operations and Results

Significant progress was made by Peplin on a number of fronts during the six month period to 31 December 2003. Highlights included:

#### **Final stages of our pre-IND activities**

Peplin's primary focus during the period has been completion of activities under Peplin's development collaboration with Allergan for our lead product PEP005 as a topical therapy for actinic keratosis (AK) and non-melanoma skin cancer (NMSC) ahead of a filing of an investigational new drug (IND) application. A significant number of studies, analyses and reports have been funded and completed by Peplin. Allergan expects to file an IND application with the US Food and Drug Administration (FDA) and thereafter initiate a Phase I/II proof of concept clinical trial in diseased patients in the second quarter of calendar 2004. Allergan as the sponsor of the IND will file the application with the FDA and Allergan will be responsible for the product's clinical development. As a result, Peplin's financial commitments under this agreement going forward will decline significantly.

#### **Receipt of initial quarterly development payment from Allergan**

During the half ended 31 December 2003, Peplin received US\$500,000 as the first equal quarterly instalment of the development payment for 2004 from Allergan. Peplin also received other amounts from Allergan during the half for pre-clinical product development.

Peplin received an upfront payment of US\$1 million on signing the development collaboration and licence agreement with Allergan in the corresponding period last year and may receive up to a further US\$22 million comprising milestone payments and development payments before commercialisation by Allergan. Thereafter Peplin may receive royalty payments on net sales. The next milestone under the collaboration agreement will be the IND filing, with further milestones on commencement of Phase III clinical trials, NDA filing and NDA approval.

#### **Promising progress on leukemia**

As announced in September 2003, a Peplin contract research group based at Birmingham University in the UK has produced promising results evaluating our lead compound PEP005 as a potential systemic therapy for the treatment of leukemia. In discrete *ex vivo* experiments conducted using primary blast cells cultured from patients suffering from refractory acute myelogenous leukemia (AML) we have observed anti-cancer effects of PEP005 at very low concentrations. This research program is ongoing and continues to deliver on its early promise of a potential systemic therapy for this very serious and poorly treated cancer condition. A systemic (intravenous) formulation of PEP005 would leverage the investment already made in the pre-clinical evaluation of the topical formulation of PEP005.

# PEPLIN BIOTECH LIMITED AND CONTROLLED ENTITIES

## DIRECTORS' REPORT

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### 2. Review of Operations and Results (cont)

#### **Acquisition of a portfolio of potential therapeutic products**

Peplin announced in November 2003 the acquisition of the rights to a portfolio of research stage compounds comprising engineered polyunsaturated fatty acids (EPUFA), with potential therapeutic utility in conditions such as cardiovascular disease, complications of diabetes, pain, inflammation and cancer. We have been planning the research and development pathway for this very interesting portfolio of potential products which will enhance both the diversity of compounds Peplin has under development and the disease states which we address.

#### **Management changes**

There have been significant changes to the management team at Peplin. Compared with 12 months ago, there are five new faces and the team has grown by three. In September 2003 we announced the appointment of our new Managing Director and CEO, Michael Aldridge to replace Garry Redlich and in December 2003 we announced the appointment of Phil Baker as CFO and Company Secretary replacing David Craig. Other new faces comprise three manager level appointees to oversee our patent portfolio, our contract production and manufacturing operations and our anti-cancer development programs.

#### **Successful financing**

In October 2003, following shareholder approval at our AGM, we closed the second tranche of a two tranche institutional financing. In total Peplin issued 6,500,000 shares at \$0.88 per share raising \$5.72 million. We were very pleased by the level of institutional support we received in the financing and the quality of the institutions added to the register.

#### **Financial results**

Peplin's net loss before and after tax for the six months to 31 December 2003 was \$3,938,054 compared with a net loss of \$264,713 for the corresponding period last year.

Revenue for the six months to 31 December 2003 was \$2,199,427 comprising the above mentioned payments from Allergan, Government grants under the R&D Start program and interest earned on cash deposits. Total revenue was \$178,764 lower than for the corresponding period which included the US\$1 million initial up-front fee from Allergan.

Research & development expenses increased to \$5,303,343 in the six month period to 31 December 2003 from \$1,695,578 in the comparable period the previous year. This reflects the significant step up in investment we made during this period and arises principally from:

- increased contracted R&D activities primarily relating to PEP005 pre-clinical toxicology, topical PEP005 product formulation development and manufacturing process development and optimization (some of which was funded by Allergan). Most of this contract work was completed by 31 December 2003; and
- a decision by the Board to fully amortise the acquisition costs of the EPUFA portfolio of potential therapeutic products.

General and administrative expenses continue to be contained, with expenses falling by \$110,669 to \$833,411 in the six month period to 31 December 2003 as compared with the corresponding period (which included some one off costs associated with closing the Allergan agreement).

Peplin's cash balance at 31 December 2003 was \$9,144,229 with current liabilities of \$2,232,758.

# PEPLIN BIOTECH LIMITED AND CONTROLLED ENTITIES

## DIRECTORS' REPORT

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### 2. Review of Operations and Results (cont)

#### **Future Obligations**

We now have reduced ongoing obligations under our collaboration with Allergan to undertake certain pre-clinical activities in support of a new drug application (NDA) filing with the FDA. Importantly, our research and development activities directly relating to our topical therapy for AK and NMSC are outsourced and will decline significantly going forward with a commensurate reduction in cash outflows. At the same time, Peplin has now received its initial quarterly instalment of the development payment for 2004 from Allergan and will receive further instalments during 2004, subject to Peplin continuing to comply with its obligations under the agreement. These factors, coupled with our cash-on-hand, mean that Peplin is positioned to meet future obligations, to develop PEP005 and related compounds for other cancer types and to advance the recently acquired EPUFA product portfolio.

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

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Michael Aldridge  
Managing Director

Brisbane, Queensland  
Dated this tenth day of February, 2004

**PEPLIN BIOTECH LIMITED AND CONTROLLED ENTITIES**  
**CONSOLIDATED STATEMENT OF FINANCIAL PERFORMANCE**  
**FOR THE HALF-YEAR ENDED 31 DECEMBER 2003**

|  | Note  | Half-year<br>31 Dec 2003<br>\$ | Half-year<br>31 Dec 2002<br>\$ |
|--|-------|--------------------------------|--------------------------------|
| Revenues from ordinary activities                              |       |                                |                                |
| Grants   |       | 577,087                        | 502,701                        |
| Interest   |       | 147,916                        | 93,600                         |
| Licence fee  | 3 (a) | 764,526                        | 1,781,890                      |
| Product development charges                                    | 3 (b) | 688,970                        | -                              |
| Other income   |       | 20,928                         | -                              |
| Total revenues from ordinary activities                        |       | <u>2,199,427</u>               | <u>2,378,191</u>               |
| Expenses from ordinary activities                              |       |                                |                                |
| Research and development                                       | 3 (c) | (5,303,343)                    | (1,695,578)                    |
| General and administrative                                     | 3 (d) | (833,411)                      | (944,080)                      |
| Borrowing costs  |       | (727)                          | (3,246)                        |
| Total expenses from ordinary activities                        |       | <u>(6,137,481)</u>             | <u>(2,642,904)</u>             |
| <b>Loss from ordinary activities before income tax expense</b> |       | <b>(3,938,054)</b>             | <b>(264,713)</b>               |
| Income tax expense   |       | -                              | -                              |
| <b>Net loss</b>  |       | <b><u>(3,938,054)</u></b>      | <b><u>(264,713)</u></b>        |
| Basic earnings per share (loss)                                |       | (5.8)¢                         | (0.5)¢                         |
| Diluted earnings per share (loss)                              |       | (5.8)¢                         | (0.5)¢                         |

The above consolidated statement of financial performance should be read in conjunction with the accompanying notes.

**PEPLIN BIOTECH LIMITED AND CONTROLLED ENTITIES**

**CONSOLIDATED STATEMENT OF FINANCIAL POSITION**

**AS AT 31 DECEMBER 2003**

|                               | <b>31 Dec<br/>2003<br/>\$</b> | <b>30 June<br/>2003<br/>\$</b> |
|-------------------------------|-------------------------------|--------------------------------|
| <b>Current Assets</b>         |                               |                                |
| Cash assets                   | 9,144,229                     | 6,399,620                      |
| Receivables                   | 355,724                       | 131,936                        |
| Other assets                  | 93,678                        | 136,788                        |
| Total Current Assets          | <u>9,593,631</u>              | <u>6,668,344</u>               |
| <b>Non-Current Assets</b>     |                               |                                |
| Property, plant and equipment | 381,412                       | 224,690                        |
| Intangible assets             | 3,762,629                     | 3,897,576                      |
| Total Non-Current Assets      | <u>4,144,041</u>              | <u>4,122,266</u>               |
| <b>Total Assets</b>           | <u>13,737,672</u>             | <u>10,790,610</u>              |
| <b>Current Liabilities</b>    |                               |                                |
| Payables                      | 2,063,194                     | 884,994                        |
| Interest-bearing liabilities  | -                             | 23,079                         |
| Provisions                    | 69,065                        | 71,214                         |
| Other liabilities             | 100,499                       | 249,054                        |
| Total Current Liabilities     | <u>2,232,758</u>              | <u>1,228,341</u>               |
| <b>Total Liabilities</b>      | <u>2,232,758</u>              | <u>1,228,341</u>               |
| <b>Net Assets</b>             | <u>11,504,914</u>             | <u>9,562,269</u>               |
| <b>Equity</b>                 |                               |                                |
| Contributed capital           | 25,042,194                    | 19,161,495                     |
| Accumulated losses            | <u>(13,537,280)</u>           | <u>(9,599,226)</u>             |
| <b>Total Equity</b>           | <u>11,504,914</u>             | <u>9,562,269</u>               |

The above consolidated statement of financial position should be read in conjunction with the accompanying notes.

**PEPLIN BIOTECH LIMITED AND CONTROLLED ENTITIES**

**CONSOLIDATED STATEMENT OF CASH FLOWS**

**FOR THE HALF-YEAR ENDED 31 DECEMBER 2003**

|  | Half-year        |                  |
|--|------------------|------------------|
|  | 31 Dec 2003      | 31 Dec 2002      |
|  | \$               | \$               |
| <b>Cash Flows from Operating Activities</b>          |                  |                  |
| Cash receipts in the course of operations            | 1,817,881        | 2,117,651        |
| Cash payments in the course of operations            | (4,483,949)      | (2,770,721)      |
| Interest received                                    | 119,158          | 87,368           |
| Borrowing costs paid                                 | (727)            | (3,246)          |
|  | <hr/>            | <hr/>            |
| <b>Net cash used in operating activities</b>         | (2,547,637)      | (568,948)        |
|  | <hr/>            | <hr/>            |
| <b>Cash Flows from Investing Activities</b>          |                  |                  |
| Payments for plant and equipment                     | (203,302)        | (7,003)          |
| Proceeds from disposal of plant and equipment        | 20,928           | -                |
| Payments for intellectual property                   | (225,000)        | -                |
|  | <hr/>            | <hr/>            |
| <b>Net cash used in investing activities</b>         | (407,374)        | (7,003)          |
|  | <hr/>            | <hr/>            |
| <b>Cash Flows from Financing Activities</b>          |                  |                  |
| Proceeds from issues of shares                       | 6,011,500        | 4,388,500        |
| Share issue transaction costs                        | (288,801)        | (214,898)        |
| Repayment of borrowings                              | (23,079)         | (7,863)          |
|  | <hr/>            | <hr/>            |
| <b>Net cash provided by financing activities</b>     | 5,699,620        | 4,165,739        |
|  | <hr/>            | <hr/>            |
| <b>Net increase in cash held</b>                     | 2,744,609        | 3,589,788        |
| <b>Cash at the beginning of the reporting period</b> | 6,399,620        | 2,168,055        |
|  | <hr/>            | <hr/>            |
| <b>Cash at the end of the reporting period</b>       | <u>9,144,229</u> | <u>5,757,843</u> |

The above consolidated statement of cash flows should be read in conjunction with the accompanying notes.

**PEPLIN BIOTECH LIMITED AND CONTROLLED ENTITIES**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**  
**FOR THE HALF-YEAR ENDED 31 DECEMBER 2003**

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**1. Basis of Preparation of Half-Year Financial Report**

This general purpose financial report for the interim half-year reporting period ended 31 December 2003 has been prepared in accordance with Accounting Standard AASB 1029: *Interim Financial Reporting*, other mandatory professional reporting requirements (Urgent Issues Group Consensus Views), other authoritative pronouncements of the Australian Accounting Standards Board and the Corporations Act 2001.

This interim financial report does not include all the notes of the type normally included in an annual financial report. Accordingly, this report is to be read in conjunction with the annual report for the year ended 30 June 2003 and any public announcements made by Peplin Biotech Limited during the interim reporting period in accordance with the continuous disclosure requirements of the Corporations Act 2001.

The accounting policies adopted are consistent with those of the most recent annual financial report.

**2. Segment Information**

The consolidated entity predominantly operates in one business segment. Its activities comprise research and development of therapeutic products for the treatment of cancers and other diseases.

The consolidated entity predominantly operates in one geographical segment, being Australia.

**3. Individually Significant Items**

Individually significant items included in expenses from ordinary activities:

|  | Half-year      |                |
|--|----------------|----------------|
|  | 31 Dec<br>2003 | 31 Dec<br>2002 |
|  | \$             | \$             |
| 3 (a) Licence fee:   |                |                |
| Initial quarterly instalment of development payment<br>(US\$500,000 at hedged rate)                | 764,526        | -              |
| Initial upfront payment (US\$1,000,000)  | -              | 1,781,890      |
| 3 (b) Product development charges:   |                |                |
| Payments by licensee for pre-clinical product development  | 688,970        | -              |
| 3 (c) Amortisation of patents purchased during the period  | 383,000        | -              |
| 3 (d) Consulting services for commercialisation of the R&D<br>programme and subsequent success fee | -              | 231,617        |

**PEPLIN BIOTECH LIMITED AND CONTROLLED ENTITIES**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**  
**FOR THE HALF-YEAR ENDED 31 DECEMBER 2003**

**4. Equity Securities Issued**

Movements in contributed capital during the half-year were as follows:

| Details   | Note | No. of Shares     | Issue Price | \$                |
|---|------|-------------------|-------------|-------------------|
| Balance – 30/06/03                              |      | 65,605,000        |             | 19,161,495        |
| Exercise of options                             | (a)  | 150,000           | 40¢         | 60,000            |
| Share placements                                | (b)  | 6,500,000         | 88¢         | 5,720,000         |
| Transaction costs arising from share placements |      |                   |             | (288,801)         |
| Share purchase plan                             | (c)  | 263,068           | 88¢         | 231,500           |
| Acquisition of patents                          | (d)  | 200,000           | 79¢         | 158,000           |
| Balance – 31/12/03                              |      | <u>72,718,068</u> |             | <u>25,042,194</u> |

- (a) During the half-year 150,000 options for ordinary shares were exercised for cash at an issue price of 40 cents for each fully paid ordinary share.
- (b) During October 2003, 6,500,000 ordinary shares were placed with investors at 88 cents per share fully paid, raising \$5,720,000 cash.
- (c) During November 2003, 263,068 ordinary shares were issued to existing investors as part of the share purchase plan at 88 cents per share fully paid, raising \$231,500 cash
- (d) During November 2003, 200,000 ordinary shares were issued at a deemed price of 79 cents as part consideration for the purchase of certain patents.

**5. Contingent Liabilities**

The consolidated entity undertakes projects in accordance with agreements with various government authorities. In return the consolidated entity receives grants from these authorities. As at 30 June 2003 the total grants received by entities in the consolidated entity (including amounts received by Peplin Trust prior to its acquisition) were \$2,631,000 (2002: \$1,808,000) of which \$5,000 (2002: \$207,000) was included in unearned revenue. A further grant of \$572,000 (2002: \$296,000) was received during the half-year (resulting in the total grants received to 31 December 2003 being \$3,203,000 (2002: \$2,104,000)). As part of the standard agreements with the government authorities, under certain circumstances the grants together with interest may be repayable. These circumstances can include the consolidated entity breaching the agreements or an insolvency event occurring. The directors do not expect that any amount will be required to be repaid.

As disclosed in Note 6 the consolidated entity has acquired a portfolio of patents relating to potential therapeutic products. Under the terms of the contractual arrangements associated with this acquisition, up to 2.3 million shares in Peplin could be issued in a series of tranches on the successful completion by Peplin to its satisfaction of key milestones in the commercial development of a drug based on the patents acquired. These milestones, if achieved, would occur over a period in excess of five years. The continuation of the research and development in relation to the patents is at Peplin's option.

**PEPLIN BIOTECH LIMITED AND CONTROLLED ENTITIES**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**  
**FOR THE HALF-YEAR ENDED 31 DECEMBER 2003**

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**6. Acquisition of Patents**

During the half-year the consolidated entity acquired a portfolio of patents relating to potential therapeutic products. The cost of the patents was as follows -

|                       |                |
|-----------------------|----------------|
|                       | \$             |
| Cash                  | 225,000        |
| Shares (refer note 4) | 158,000        |
|                       | <u>383,000</u> |

In addition, the parent entity issued 250,000 options for ordinary shares exercisable by 20 November 2005 at 79 cents each.

Due to the strict tests applying to recoverability of intangible assets and the treatment of research and development costs, the Directors have elected to fully amortise the cost of the patents in the half-year.

**PEPLIN BIOTECH LIMITED AND CONTROLLED ENTITIES**

**DIRECTORS' DECLARATION**

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The directors declare that the attached financial statements and notes:

- (a) comply with Accounting Standards, the Corporations Regulations 2001 and other mandatory professional reporting requirements; and
- (b) give a true and fair view of the consolidated entity's financial position as at 31 December 2003 and of its performance, as represented by the results of its operations and its cash flows, for the half-year ended on that date.

In the directors' opinion:

- (a) the financial statements and notes are in accordance with the Corporations Act 2001; and
- (b) there are reasonable grounds to believe that Peplin Biotech Limited 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 directors.

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Michael Aldridge  
Managing Director

Brisbane, Queensland  
Dated this tenth day of February, 2004

## **INDEPENDENT REVIEW REPORT**

### **To the Members of Peplin Biotech Limited**

#### **Scope**

We have reviewed the financial report being the Directors' Declaration, Consolidated Statements of Financial Performance, Financial Position and Cash Flows and Notes to the Consolidated Financial Statements of Peplin Biotech Limited (the company) for the half-year ended 31 December 2003. The company's directors are responsible for the financial report which includes the consolidated financial statements of the consolidated entity comprising the company and the entities it controlled at the end of the half-year or from time to time during the half-year. We have performed an independent review of the financial report in order to state whether, on the basis of the procedures described, anything has come to our attention that would indicate that the financial report is not presented fairly in accordance with Accounting Standard AASB 1029: *Interim Financial Reporting* and other mandatory financial 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 company to lodge the financial report with the Australian Securities & Investments Commission.

Our review has been conducted in accordance with Australian Auditing and Assurance Standards applicable to review engagements. The review is limited primarily to inquiries of company 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 provided is less than that 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 of Peplin Biotech Limited 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 financial reporting requirements in Australia.

**JOHNSTON RORKE**  
Chartered Accountants

**C F Jarrold**  
Partner

Brisbane, Queensland  
10 th February 2004