

PEP *Talk*

QUARTERLY REPORT TO SHAREHOLDERS
THREE MONTHS ENDED 31 DECEMBER 2004

***Funding in place to
complete phase II skin
cancer clinical trials in
Australia in 2005***



Peplin

Pharmaceuticals for Life

HIGHLIGHTS FOR THE DECEMBER QUARTER

- New name and corporate identity:** At the 2004 AGM Peplin's shareholders approved the change of company name from Peplin Biotech Ltd to Peplin Limited. This was confirmed by ASIC in early October 2004. The change of name aligns the company's public image and profile with its vision. We are moving beyond being a research based discovery engine to a more complete pharmaceutical product development company. In addition, the company adopted a new brand statement: *Pharmaceuticals for Life* to articulate our mission of developing therapeutic products which help people with cancer live healthier, happier and longer lives.
- Reacquired PEP005 Topical:** In early October 2004, following a four day period in which Peplin suspended its shares from trading, we announced an initiative to resume control of PEP005 Topical. We took this step to ensure the timely progress of PEP005 Topical into later stage clinical trials. Allergan confirmed that its decision to allow us to reacquire PEP005 Topical was not based on any concerns over PEP005 Topical's safety or efficacy but was a prioritisation issue as it managed its development portfolio.
- Underwritten \$10.2 million rights issue:** In November 2004, we announced a fully underwritten renounceable rights issue to shareholders to purchase one new share at \$0.42 per share for every three shares held. The issue was very well supported with a 75% take-up rate among shareholders and the balance went to a number of institutional shareholders. These funds will support the three phase II clinical trials in actinic keratosis (AK) and two forms of basal cell carcinoma (BCC) which we plan to conduct during 2005.

SUMMARY DECEMBER QUARTER FINANCIALS

Cash flows	December quarter (\$'000)	Year to date (\$'000)
Net operating cash flows	(671)	(3,941)
Net investing cash flows	(108)	(237)
Net financing cash flows	9,512	9,535
Net increase in cash held	8,733	5,357
Cash position at end of quarter	12,960	

- Cash at 31 December 2004 totalled \$13.0 million.
- Net operating cash out flow of \$0.7 million during the quarter was lower than the previous quarter (\$3.3 million) mainly as a consequence of the receipt of US\$1.3 million from Allergan upon termination of the collaboration and license agreement in October 2004 and lower expenditure on R&D (\$2.9 million compared with \$3.8 million).
- R&D was primarily focused on the final studies to complete the pre-clinical package for PEP005 IC, our bladder cancer product, and pre-clinical studies required for PEP005 IV, our leukaemia product, together with analysis and reporting of results of the phase I clinical trial on PEP005 Topical and preparations for the forthcoming phase II clinical trials.
- During the December quarter Peplin received the final instalment (\$0.2 million) under the Australian Federal Government's R&D Start program for PEP005 Topical.

IMPORTANT EVENTS SINCE THE END OF THE DECEMBER QUARTER

- **Positive results from phase I clinical trial:** On 10 January 2005, we were very pleased to announce the results of the phase I clinical trial of PEP005 Topical which had been ongoing at the time we reacquired PEP005 Topical from Allergan. The trial studied the safety of a single application of PEP005 Topical to five AK lesions on the shoulders, chest, back and arms of 16 patients followed by a post treatment follow-up period lasting at least two weeks compared to a vehicle control (placebo).

We were pleased to be able to document a favourable safety profile of the drug in the skin with all local skin responses mild and as expected. Unexpectedly, the trial demonstrated positive indications of PEP005 Topical's ability to clear lesions with 40% of treated lesions either completely cleared or almost cleared. This compares with 15% of lesions treated with placebo. One patient saw all five of his lesions completely cleared by a single application of PEP005 Topical while another saw four of his five lesions completely cleared – all within 21 days after treatment.

These results fundamentally validate our decision late last year to reacquire PEP005 Topical and secure funding for the important phase II stage of its development.

- **Contract clinical development collaboration:** On 19 January 2005, we announced a collaboration with Cvitkovic & Associates Consultants S.A. (CAC) to provide contract clinical development services to Peplin. CAC is based in Paris, France and is a cancer focused contract research organisation. This collaboration will bring world-class international expertise to Australia for the imminent phase II stage of PEP005 Topical's clinical development.
- **Discussions with potential partners:** We have initiated and will be continuing discussions with international pharmaceutical companies exploring the potential for an attractive, long term collaborative relationship for the development and commercialisation of PEP005 Topical. This initiative is in parallel and consistent with our current independent clinical development program.

PLANS FOR THE MARCH QUARTER

- **Initiation of phase II clinical trials:** Peplin is firmly on track for the three phase II clinical trials of PEP005 Topical. Peplin expects these trials to commence in March. There will be three concurrent phase IIa clinical trials enrolling a total of 180 patients across 11 clinical centres in Australia. One trial is in AK and two trials in superficial and nodular forms of BCC.
- **Expenditure:** Major expenditures expected for the pending quarter will relate to manufacturing of

clinical trial supplies of PEP005 Topical and preparing for the initiation of the three phase II trials due to commence this quarter. Peplin is well positioned to fund its 2005 phase II clinical development program.

Michael Aldridge
Managing Director & Chief Executive Officer
8 February 2005

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To register for this service simply visit the Computershare website at www.computershare.com and:

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PEPLIN OVERVIEW

MISSION

We are dedicated to the discovery and development of prescription therapeutic products which allow people with cancer and other diseases with limited therapeutic options to live healthier, happier and longer lives.

Our people, our contractors and our collaborative relationships are our greatest assets and we recognise and reward their contribution to our success.

VISION

Peplin's vision is to deliver superior returns to shareholders through a focus on discovering, developing and commercialising therapeutic products for the global market.

Peplin's first goal is to dominate the skin cancer market by delivering a novel product which drives a paradigm shift in the treatment of skin cancer. Peplin will build on that foundation to deliver market leading products for other fields of cancer and other diseases which have limited therapeutic options.

BUSINESS

Peplin Limited is a public company based in Brisbane, Australia, focused on the discovery, development and commercialisation of proprietary pharmaceutical products for the treatment of cancer.

Peplin has a patent protected technology comprising a new class of naturally occurring molecules which,

together with a synthetically modified version, show significant potential as anti-cancer agents for a wide range of human cancers. Peplin's lead molecule in this technology is PEP005, which is chemically described as 3-angeloyl ingenol. PEP005 has demonstrated powerful anti-cancer effects by way of a unique mode of action, and is the first in its class of molecule to be taken into clinical development.

Peplin's lead product is PEP005 Topical which is being developed for the topical treatment of actinic keratosis (AK), a pre-cancerous lesion or sun spot, and basal cell carcinoma (BCC), the most common form of skin cancer. Peplin has filed Investigational New Drug (IND) applications with the US Food and Drug Administration (FDA) and completed a phase I clinical trial of PEP005 Topical. Peplin holds global rights to PEP005 Topical and all rights worldwide to other cancer applications of PEP005.

Peplin's earlier stage pipeline is targeted at bladder cancer using PEP005 in an intra-cavitary or intravesical formulation (PEP005 IC) and leukaemia (a blood borne cancer) using an intravenous formulation (PEP005 IV). Its portfolio of engineered polyunsaturated fatty acid (EPUFA) compounds opens additional potential opportunities in cancer and adds candidates for cardiovascular disease, pain, inflammation and diabetic complications.

PRODUCTS IN DEVELOPMENT

Product	Disease	Research	Pre-clinical	Clinical
PEP005 Topical	AK and BCC	▶		
PEP005 IC	Superficial bladder cancer	▶		
PEP005 IV	Leukaemia	▶		
PEP006, 008, 010	Anti-cancer	▶		
EPUFAs	Cardiovascular, diabetic complications, inflammation, pain and cancer	▶		

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