

# PEP *Talk*

QUARTERLY REPORT TO SHAREHOLDERS  
THREE MONTHS ENDED 30 September 2006

*Major international capital  
raising with blue chip investors*

## HIGHLIGHTS

- \$40 million raised in financing deal led by global healthcare investor MPM Capital
- New appointments bring international drug development expertise to board and management
- Manufacturing plant opened in Queensland
- Continuing positive results from clinical trials



**Peplin**

*Pharmaceuticals for Life*

## THE SEPTEMBER QUARTER \$40 MILLION INTERNATIONAL FINANCING

A significant highlight of the third quarter 2006 was the closing of a \$40 million financing deal lead by MPM Capital, a biotechnology focused global venture capital and investment management firm based in the United States.

An international placement of 37.5 million shares at \$0.71 per share and 11.25 million four year options raised approximately \$26.6 million. Other investors in the placement include Deerfield Capital Management, Orbis, AMP Capital and First Choice. The international deal closed alongside a fully underwritten non-renounceable rights issue of approximately 19.6 million new shares to Peplin shareholders at \$0.71 per share together with 5.9 million four year options, raising approximately \$13.9 million.

The capital raising follows encouraging results in early phase II clinical trials of PEP005 in the treatment of actinic keratosis (AK) and basal cell carcinoma (BCC), which showed that just two days of treatment were effective in clearing the majority of skin lesions.

### THE CAPITAL RASING FOLLOWS ENCOURAGING RESULTS IN PHASE II CLINICAL TRIALS

“The excellent results reported in our recent clinical trials are viewed by MPM as central to our future success and provide a strong rationale for their investment,” according to Peplin Managing Director and CEO Michael Aldridge.

The international placement was structured in two equal tranches. The second tranche was contingent on the results of a standard safety trial to evaluate the potential of PEP005 to cause skin sensitisation reactions. That trial has since concluded successfully and the second tranche has now closed as of 1 November 2006.

On a pro-forma basis following the financing, Peplin's cash position stood at almost \$52 million. The company is well capitalized to deliver results of phase II testing in AK and BBC and now enjoys the support of Blue Chip international investors.

As well as access to funding and credibility in international capital markets, the MPM Capital relationship provides

Peplin with access to important expertise in drug development and is consistent with the company's corporate strategy of building its operations in the North American market.

### THE MPM RELATIONSHIP PROVIDES PEPLIN WITH ACCESS TO IMPORTANT EXPERTISE IN DRUG DEVELOPMENT

As part of the international financing, Peplin has appointed two new directors to join its board: Jim Scopa, a general partner with MPM with significant experience in capital markets and financing drug development; and Eugene Bauer former dean of Stanford Medical School and a highly-regarded US dermatologist.

“The ability to attract individuals with these skills, experience and networks is testament to the value of the MPM Capital relationship,” according to Peplin Chairman Cherrell Hirst.

MPM Capital is considered one of the foremost biotechnology investment firms in the world with more than US\$2 billion under management. The firm is recognised for its specialisation in biopharmaceutical and medical devices and its principals and advisors are drawn from the healthcare industry. It has offices in Boston and San Francisco.

Peplin has outlined the strategic importance of targeting the North American market in its 2005 annual report and in a webcast in March 2006 (see the investor information section of Peplin's website, [www.peplin.com](http://www.peplin.com)).

North America is an important focus for Peplin for a number of reasons: Peplin's late stage product development activities will require further capital and the US offers large capital markets at low cost; it is the largest market for prescription pharmaceutical products, particularly for a product that treats skin lesions in a cosmetically attractive way; the US is home to the most experienced pharmaceutical product development managers, consultants and contractors; and it is the most likely location for potential corporate partners.

## SUMMARY SEPTEMBER QUARTER FINANCIALS

Cash flows	September quarter (\$'000)	Last four quarters (\$'000)
Net operating cash flows	(4,239)	(13,510)
Net investing cash flows (excl. term deposits)	(191)	(1,533)
Net financing cash flows	4,632	34,629
Net increase / (decrease) in cash held	148	19,586
Cash position at end of quarter (incl. term deposits)	31,339	

- Cash-on-hand (including cash on short-term deposit) at 30 September 2006 totalled \$31.3 million, down from \$31.2 million at 30 June 2006.
- Net operating cash outflow during the quarter of \$4.3 million was invested primarily in the phase IIb AK clinical trial, pre-clinical toxicology and related activities.
- Net financing cash flows during the September quarter increased to \$4.6 million due to the receipt of proceeds from the underwritten pro-rata entitlement offer announced on 24 May 2006.

## PEPLIN LAUNCHES US OPERATIONS

Peplin announced in June that it had incorporated Peplin Operations USA, Inc as a wholly owned subsidiary. The move is consistent with the company's ongoing strategy of building out its late stage product development capabilities in North America.

In addition, Peplin announced the appointment of three new members to its senior management team, to be based in an office established in the San Francisco Bay Area. Peplin has appointed Philip Moody as Chief Financial Officer and VP Finance and Operations, Gary Patou as Chief Medical Officer and Cheri Jones to the position of Vice President Regulatory Affairs. Managing Director and CEO Michael Aldridge will also permanently relocate to the US at an appropriate time.

Ms Jones is a drug regulatory affairs professional with extensive experience with FDA. Most recently she successfully obtained three New Drug Application (NDA) approvals for QLT. Ms Jones has also worked for Obagi Medical Products, Valeant Pharmaceuticals, ALpharma, Goldline and Bristol-Myers.

Dr Patou is an Executive Partner at MPM Capital and has broad experience in drug development, most recently as Executive Vice President and Chief Medical Officer of Oscient Pharmaceuticals. He has also worked in senior positions for Genesoft Pharmaceuticals where he was instrumental in obtaining FDA approvals, and at SmithKline Beecham Pharmaceuticals.

Mr Moody was previously Vice President, Finance and Operations at Chiron Corporation. The California-based company was one of the larger biotechnology companies in the world with an annual revenue of \$US1.7 billion. It was acquired by Novartis AG in late 2005. Mr Moody will oversee the development of Peplin's US operations.

## CLINICAL TRIAL CONFIRMS CLEARANCE RATES

Peplin recently announced a 70% clearance rate for actinic keratosis (AK) lesions in its US phase IIa dose escalation clinical trial of PEP005 Topical.

Two applications of the gel on two consecutive days cleared 70% of the lesions of patients treated at the maximum tolerated dose (MTD). Subjects were followed for a further four weeks or until all skin responses had resolved.

Managing Director and CEO Michael Aldridge said the results correlated closely with clearance rates in previous clinical trials of PEP005.

"Interestingly, we saw the clearance rates in this study in just four to six weeks after treatment. That is very rapid."

The primary goal of the study was to confirm the MTD of the drug. Preliminary results announced in February established that the MTD was 0.05%.

AK skin lesions are characterised by rough, red, scaly patches, crusts or sores on the top layer of the skin. They are the most common pre-cancerous skin lesion, affecting 50% of Caucasians over the age of 40 years.

Treatment of AK lesions is currently the most common dermatologic procedure performed in an out-patient setting. Current treatments such as cryotherapy or other topical medications can cause scarring, can be inconvenient or require long treatment times.

## FEDERAL MINISTER OPENS NEW FACILITY

The Federal Minister for Industry, Tourism and Resources Ian Macfarlane opened Peplin's new manufacturing facility for the production of PEP005 in Southport Queensland on July 20.

The facility was custom built to integrate Peplin's extraction and purification technology into a single site with commercial scale capacity. The facility has commenced production of PEP005.

Queensland horticulturalists grow and harvest radium weed. At the new facility the plant is dried and extracted in ethanol and then converted into a crystalline powder. The powder is sent to the UK to be formulated into a topical gel.

"Peplin is a stand-out example of a successful local drug development company putting Australian innovation to work," Mr Macfarlane said at the opening of the site. "The opening brings together R&D successes and a manufacturing plant."

## SAFETY CONFIRMED IN CLINICAL TRIALS

Results from the Australian phase IIa clinical trial of PEP005 Topical in nodular forms of basal cell carcinoma (nBCC) have demonstrated that the drug is safe and well tolerated.

The main goal of the trial was to investigate the safety of PEP005 Topical treatments. The study found no drug related serious adverse events.

Tumor clearance rates were dose dependent with the highest concentration of PEP005 Topical the most effective.

In the high concentration group, two applications of the drug cleared 25% of nBCC tumours. Nodular carcinomas are more difficult to treat than superficial carcinomas as they are situated deeper in the skin.

Sydney dermatologist and principal investigator Dr Robert Rosen said Peplin should be very pleased with the results of this trial and the body of data emerging for this agent.

"The thicker and deeper structure of nodular basal cell carcinomas makes them more difficult to clear with topical agents. Accordingly this level of activity is consistent with the higher clearance rates we saw in the previous superficial BCC trial and what we see with other topical agents," he said.

Basal cell carcinoma is the most common form of skin cancer.

## PEPLIN TESTS FOR SKIN SENSITISATION

Peplin commenced a study to evaluate the skin sensitisation of PEP005 Topical in the third quarter 2006. It is the first in a series of dermal safety clinical studies required by regulatory agencies such as FDA for all new skin products.

Skin sensitisation refers to the potential of a chemical to cause allergic contact dermatitis.

After positive results from phase II clinical trials of PEP005 in the treatment of actinic keratosis and basal cell carcinoma, Peplin considers it an appropriate time to initiate these standard safety studies.

Approximately 220 healthy volunteers were given a low concentration dose of PEP005 Topical gel. After two weeks subjects received a single challenge dose and evaluated for any evidence of skin sensitisation. The trial was conducted at a single location in the US.

Peplin has now announced the results of this study which showed no evidence of skin sensitising potential.

### NEW BOARD MEMBERS

Peplin appointed two new members to its board of directors in the third quarter 2006.

#### **JIM SCOPA**

Mr Scopa is a General Partner at MPM Capital. He has more than 18 years experience in healthcare investment banking, specialising in financings as well as mergers & acquisitions. He was previously a Partner and Co-Director of Healthcare Investment Banking at Thomas Weisel Partners. Mr Scopa has advised and raised capital globally for companies such as Axon Instruments, Fisher and Paykel Healthcare and ResMed. Mr Scopa is based in MPM's San Francisco office.

#### **EUGENE BAUER MD**

Dr Bauer is a Lucy Becker Professor, Emeritus, in Stanford University's School of Medicine. He served as Dean of the School of Medicine from 1995 to 2001, and Chair of the Department of Dermatology from 1988 to 1995. He is Chief Executive Officer of Neosil, a privately held dermatology company, and cofounder and emeritus member of the board of directors of Connetics, a publicly traded dermatology company.

## PLANS FOR THE DECEMBER 2006 QUARTER

- **Phase IIb actinic keratosis (AK) trial:** A phase IIb clinical trial of PEP005 Topical for the treatment of AK was initiated in the third quarter.

The trial is being conducted in the US at approximately 20 clinical centres and will include about 200 patients.

The aim of the trial is to confirm the safety and efficacy of the drug as a prescription medication applied by the patient in the home. It will be applied to lesions and the surrounding sun damaged skin once a day on two or three consecutive days.

- **Phase IIb superficial basal cell carcinoma (sBCC) trial:** Peplin expects to commence a phase IIb trial to evaluate the maximum tolerated dose of PEP005 in the treatment of sBCC. It will be applied to patients in the clinicians office.

The trial will be conducted in the US under Peplin's open IND with FDA

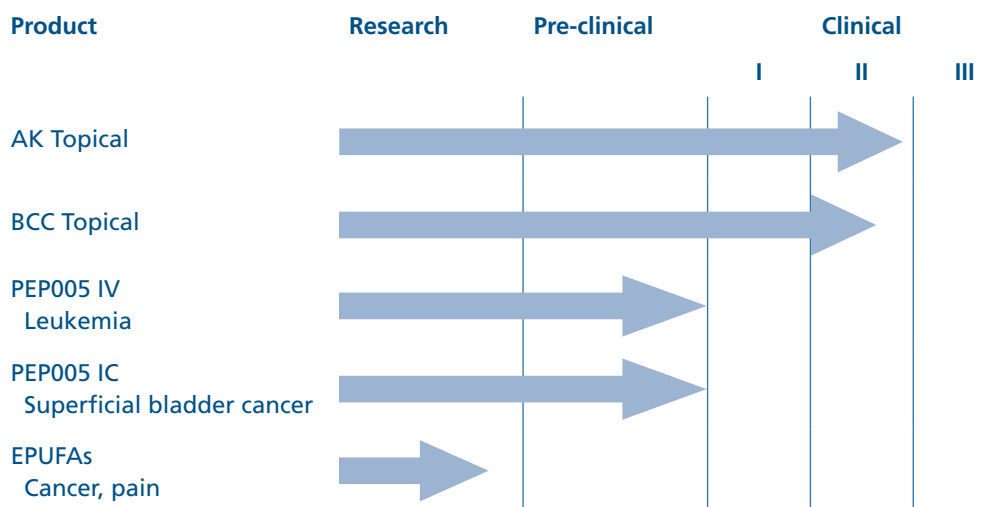
- **Follow-up of squamous cell carcinoma in situ (SCCIS) pilot clinical trail:** Peplin has completed enrollment of patients in its Australian pilot phase II clinical trial of PEP005 for the treatment of SCCIS.

The trial was initiated in May following positive results from the phase IIa clinical trial in superficial basal cell carcinoma (sBCC). The application PEP005 Topical gel on two consecutive days cleared 71% of skin tumours.

The study will be conducted by dermatologists at two sites in Queensland and one in NSW. Peplin expects to announce preliminary results in the first quarter of 2007.

Michael Aldridge  
Managing Director & Chief Executive Officer  
16 November 2006

## PRODUCTS IN DEVELOPMENT



To help reduce the cost of paper, printing and postage, you can receive an e-mail notifying you of the release of company announcements, reports and other information. The e-mail will contain a convenient link to the information on Peplin's website.

To register for this service shareholders can simply visit the Computershare website at [www.computershare.com](http://www.computershare.com) and:

- click on **Investors**,
- click on **Email address update**,
- enter **PEP** in the field,
- enter your holder identification number (**HIN**) or Security Reference Number (**SRN**), name and postcode, and
- click **Submit** and follow the prompts.

An e-mail will be sent to you for confirmation. Simply click on **reply** and then **send**.

If you have registered at [www.peplin.com](http://www.peplin.com) to receive our PEPupdates, you will continue to receive these.

## PEPLIN OVERVIEW

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### Vision

We are dedicated to the development of prescription therapeutic products which allow people to live healthier, happier and longer lives.

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

Peplin's first goal is to exploit the skin cancer market by delivering a novel product for the treatment of skin cancer and pre-cancerous conditions.

### Business

Peplin Limited is a public company focused on the development and commercialisation of medical dermatology products and in particular a novel topical product to treat skin cancer and pre-cancerous lesions. Its shares are listed on the Australian Stock Exchange (ASX) using the ticker PEP. The company is headquartered in Brisbane, Queensland with product development operations in Emeryville, California and a manufacturing facility in Southport, Queensland.

### Technology

Peplin has a patent protected technology comprising a new class of naturally occurring molecules which show significant potential as anti-cancer agents for a wide range of human cancers. Peplin's lead compound in this technology is PEP005, which has demonstrated powerful anti-cancer effects by way of a unique mode of action, and Peplin is the first to take this class of molecule into clinical development. Peplin holds global proprietary rights to the use of PEP005.

### Lead product

Peplin's lead compound is PEP005, the first in a new class of investigational agents. Peplin's lead product has shown significant promise in phase II clinical trials as a topical agent for the treatment of actinic (solar) keratosis (AK), a very common pre-cancerous lesion, and basal cell carcinoma (BCC), the most common form of skin cancer. Peplin believes the unique benefits of its lead product may include a very short course of therapy and a transient and favourable side effect profile.

### Market opportunity

PEP005's market opportunity is significant. AKs are the most common pre-cancerous skin lesions worldwide and the treatment of AKs is the most common dermatologic procedure performed in the out-patient setting.

In the US each year there are about 8.2 million procedures for AK. AK affects more than 58 million North Americans. The worldwide prevalence of AK is highest in Australia. AKs typically occur on sun damaged skin of Caucasians older than 40 years.

Non-melanoma skin cancer is the most common form of cancer worldwide. It affects more than 1.2 million people per year in the US. According to the Cancer Council Australia of all cancers NMSC is the biggest burden on the healthcare system accounting for \$232 million per year in treatment costs. Peplin is developing PEP005 to address the highly attractive and significant global market opportunity for non-surgical approaches to the treatment of AK and NMSC.

Leukemia is a cancer of the blood and blood forming organs. The Leukemia & Lymphoma Foundation estimated there would be 34,810 new cases of leukemia in the US in 2005. According to the Leukaemia Foundation in Australia there are 2,370 people diagnosed with leukemia each year.

The most common type of leukemia is acute myeloid leukemia or AML which was estimated to strike 11,960 people in the US during 2005. AML is both the most common and the most devastating form of leukemia with a 5 year survival rate of less than 20%.

### Pipeline

Peplin's earlier stage pipeline is targeted at leukemia (a blood borne cancer) using its lead compound PEP005 in an intravenous formulation (PEP005 IV) and bladder cancer using an intra-cavitary or intravesical formulation (PEP005 IC). PEP005 has demonstrated selective and potent anti-leukemia activity in pre-clinical disease models. PEP005 induces apoptosis in leukemia cells via the activation of PKC delta. Peplin holds global proprietary rights for PEP005.