



ASX AND MEDIA RELEASE

First half financial results

- **Major international financing with high profile investors**
- **\$40 million cash balance to fund advanced development programs**
- **Successful establishment of US operations**
- **Positive progress in product development**
- **Significant growth in company expertise and scope of activities**

BRISBANE, Australia, 14 February 2007 Peplin Limited (ASX:PEP) today announced results for the six month period ended 31 December 2006. As at the half year end Peplin reported a cash balance of \$39.5 million confirming its strong position to fund its ongoing program of phase II clinical trials of PEP005 Topical its proprietary product being developed to treat actinic (solar) keratosis (AK) and basal cell carcinoma (BCC).

Peplin's net loss before and after tax for the six months was \$10.4 million compared with a net loss of \$5.9 million for the corresponding period last year. Operating cash outflow, primarily representing investment in the clinical development of PEP005 Topical, was \$8.4 million compared to \$5.1 million for the corresponding period last year.

Peplin Chief Executive Officer Michael Aldridge said he was very pleased with the company's significant achievements and financial performance during the half year, particularly the major international financing and progress with the phase II development of PEP005 Topical.

"Following the financing completed during the half year, Peplin enjoys the support of major international investors who have recognised the significant potential value of our product candidates. We are now well capitalised to aggressively continue our product development programs and to grow and enhance our company's capabilities," he said.

"We are pleased with the progress demonstrated in the development of PEP005 Topical for AK and BCC and establishment of our US office facility in Emeryville in the San Francisco bay area," he said.

Mr Aldridge said that Peplin currently has four clinical trials for AK and skin cancer at various stages which are expected to complete and report during the course of 2007.

Research and development expenditure increased by \$4.4 million to \$9.3 million compared to the corresponding period last year. Major components comprised:

- the successful initiation and progress of a 200 subject US based phase II AK clinical trial;
- planning activities for a US based phase II BCC clinical trial and an Australasian based phase II AK clinical trial;

- the commencement of licensed PEP005 production at Peplin's new manufacturing facility that was opened in July 2006; and
- on-going preclinical pharmacology and toxicology studies of PEP005 for both the skin cancer and leukemia applications.

General and administrative expenses increased to \$2.4 million in the six month period to 31 December 2006 from \$1.2 million in the comparable period of the previous year, primarily due to increased staff numbers and the establishment of the US office.

Important activities during the half year included:

- **Completion of major international financing:** During the period the company successfully completed an international placement together with an entitlement offering to all Peplin shareholders. This financing was initially announced on 24 May 2006 and was made possible by the positive results in early clinical trials for AK and BCC. The combined financing raised approximately \$40.5 million through the issuance of 57.1 million shares at \$0.71 per share together with 17.1 million options exercisable at \$0.84 per share.
- **Start of US based phase IIb AK clinical trial:** During the period the company initiated PEP005-006, its multi-centre, 200 patient phase IIb clinical trial in the United States to evaluate the safety and efficacy of PEP005 Topical, its proprietary product candidate for the treatment of AK. The clinical trial, which is being conducted in the US under Peplin's open IND with FDA, will evaluate PEP005 Topical gel as a patient-applied, take-home prescription medication and build on the positive results demonstrated in Peplin's earlier AK studies, in larger patient cohorts.
- **Positive results from phase IIa nBCC trial:** In July 2006 Peplin announced positive results of its phase IIa clinical trial of patients with nodular forms of BCC. Basal cell carcinoma is the most common form of skin cancer.
- **Completion of enrolment in SCC pilot clinical trial:** In October 2006 Peplin announced that it had completed enrolment of patients in its Australian pilot phase II clinical trial of its proprietary product PEP005 Topical for the treatment of cutaneous squamous cell carcinoma in situ (SCCIS).
- **Publication of PEP005's novel anti-skin cancer mechanism:** In December 2006 Peplin published research demonstrating the novel anti-cancer mechanism of Peplin's lead compound, PEP005. This research was published in the high profile, *Journal of Immunology*, the international, peer-reviewed journal of the American Association of Immunologists.
- **Established US presence:** In September 2006 Peplin announced it had appointed Philip Moody as Chief Financial Officer and Vice President, Finance and Operations. Mr Moody brings enormous experience to Peplin's executive team, and was previously Vice President, Finance and Operations at Chiron Corporation in California.

Mr Moody, along with the earlier appointments of Cheri Jones as Vice President, Regulatory Affairs and Dr Gary Patou as Chief Medical Officer, are based in Peplin's newly opened Emeryville office in the San Francisco bay area. Michael Aldridge, Peplin's CEO, has relocated to San Francisco and will work closely with

the executive team to build Peplin's US capabilities at this critical juncture in its growth and development.

- **Opening of GMP manufacturing facility:** In July 2006 the official opening of Peplin's new state-of-the-art commercial scale manufacturing facility for the production of PEP005, its lead investigational agent for the treatment of skin cancer and leukemia, took place in Southport, Queensland. The facility is a major step towards launching a global product.

Future developments

Peplin is continuing enrollment into its US phase IIb AK study (PEP005-006) and expects to announce the results of this study in mid-2007. Peplin commenced an additional Australasian phase IIb AK study (PEP005-007) in January 2007, complimenting the PEP005-006 study and concentrating on treatment to the face and scalp.

Following the successful completion of these AK studies and subject to regulatory approval, Peplin expects to begin a phase III study in larger patient populations to progress the product to market as quickly as possible.

Peplin has announced the initiation of a second phase II clinical trial (PEP005-009) to further evaluate the safety and efficacy for the treatment of superficial forms of BCC the most common form of skin cancer. The clinical trial, which will be conducted at multiple sites in the US, will assess several dose levels of PEP005, using a dose escalation format and has the goal of optimising the dose of PEP005 Topical for this disease. Peplin intends to select an optimal dose to be evaluated in a subsequent phase III clinical trial based on an evaluation of clearance rates and local skin responses observed in this trial and subject to regulatory approval.

Peplin is also progressing its pre-clinical program focused on developing PEP005 IV for leukemia.

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ABOUT PEPLIN

Peplin is 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. 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 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. Peplin's product development activities are supported by the Australian Federal Government under its Pharmaceuticals Partnerships Program.

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 intracavitary 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 and related molecules.

ABOUT BASAL CELL CARCINOMA

Basal cell carcinoma is a cancer which develops from cells in the basal layer of the skin. It is the most common form of skin cancer accounting for ~80% of all skin cancers. Other forms of skin cancer comprise squamous cell carcinoma (~16% of cases) and melanoma (~4% of cases). BCCs typically develop on sun exposed parts of the body and are more prevalent in older Caucasians with a history of sun exposure.

In terms of incidence BCCs are the most common type of cancer found in humans. Based on a 2005 study by The Lewin Group, Inc. for The Society for Investigative Dermatology and The American Academy of Dermatology Association, there are more than one million cases of basal cell carcinoma each year in the US.

The worldwide prevalence of skin cancer is highest in Australia where it accounts for 80% of all new cancer cases diagnosed here each year. According to the Cancer Council of Australia 256,000 Australians were treated for BCC in 2002. Together, basal cell and squamous cell carcinoma are the most costly cancers in Australia, accounting for \$232 million in treatment costs per year.

ABOUT ACTINIC KERATOSIS

AK is a common skin condition characterised by rough, red, scaly patches, crusts or sores on the top layer of skin. If left untreated AKs can progress to squamous cell carcinoma, an invasive skin cancer that can be fatal. AKs usually develop on the face, lips, ears, scalp, neck, forearms and back of hands - areas that are most commonly exposed to the sun.

AKs are the most common pre-cancerous skin lesions worldwide affecting 50% of Caucasians over the age of 40 years with the average patient having 6-8 lesions. The treatment of AKs is the most common dermatologic procedure performed in the out-patient setting. Based on a 2005 study by The Lewin Group, Inc. for The Society for Investigative Dermatology and The American Academy of Dermatology Association, in the US there were 8.2 million treatments of AK in 2004. According to this study 58 million Americans have AK. The worldwide prevalence of AK is highest in Australia.

Current treatment alternatives comprise surgical techniques (primarily cryotherapy) and topical medications (e.g. 5-fluorouracil, imiquimod and diclofenac). Current treatment approaches can cause scarring and hypopigmentation at the treatment site, can be inconvenient or may require long treatment duration for effect.