



PHOSPHAGENICS

ASX Limited  
Market Announcements Office

## Phosphagenics Further Expands Pain Portfolio

- *Topical oxycodone opportunity*
- *Phosphagenics has achieved outstanding results from pre-clinical trial*
- *US\$4 billion global topical pain market*
- *Topical oxycodone to join oxycodone and oxymorphone opioid patches in 2013 clinical trials*

**20 February 2013, Melbourne, Australia:** Melbourne drug delivery technology company, Phosphagenics Limited (ASX: POH, OTCQX: PPGNY), has completed a pre-clinical study demonstrating that its oxycodone/TPM<sup>®</sup> technology can reduce local pain without the need to deliver oxycodone into the bloodstream. This discovery has significant commercial implications and the Company intends to commence clinical trials in Quarter 3 of 2013.

These trials would be additional to the current oxymorphone and oxycodone patch trials referred to in recent announcements. This product represents a further extension to Phosphagenics' pain product development program.

The finding stems from TPM's unique ability to deliver molecules in a targeted manner either into the skin or through the skin into the bloodstream, by modifying the formulation. Phosphagenics has formulated TPM<sup>®</sup> to deliver compounds into the skin for its many topical dermatological and personal care applications. In the pre-clinical study on oxycodone/TPM<sup>®</sup> for localised pain, TPM<sup>®</sup> was formulated to deliver oxycodone into the localised area of application, without spillage into the blood. This potential new application of oxycodone to local pain further broadens the Company's pain franchise.

The pre-clinical study in an appropriate pain model demonstrated a significant reduction in pain after topical application of the oxycodone/TPM<sup>®</sup> formulation, as compared to a control. The investigation also found the opioid worked rapidly and did not enter the bloodstream.

A topical opioid able to act directly on inflamed tissue, without delivery into the systemic circulation, could eliminate all side effects associated with ingestion of the oral dosage form. It would therefore represent a much safer dosage form, and may be appropriate for localised pain indications that have traditionally proven very difficult to treat. These include both post-herpetic neuralgia/shingles and diabetic neuropathy.

Phosphagenics' CEO, Dr Esra Ogru, said the company was keen to expand its pain portfolio and progress further trials of topical TPM<sup>®</sup> oxycodone technology.

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There is no topical opioid product on the market and sales of non-opioid pain drugs prescribed for localised pain exceed US\$4 billion annually. Endo Pharmaceutical's market leading topical pain product, Lidoderm™, is used to treat neuropathic pain but belongs to a different class of non-opioid analgesic compounds.

Dr Ogru said: "Delivering a powerful opioid like oxycodone topically has never been achieved commercially. It has been widely assumed that opioids can only treat pain by systemic delivery, that is, via the blood stream. Our study confirms more recent findings that opioid receptors are up-regulated in tissue in response to pain, particularly pain associated with inflammation."

Dr Ogru added: "There is no other company in the area of transdermal delivery of pain drugs progressing multiple products with multiple applications. This potential new application of oxycodone to local pain further broadens our pain franchise. We remain committed to our strategy of building a first class pain portfolio comprising a series of compounds with the ability to manage all levels of pain, with various application methods. Underpinning this entire platform is our TPM® delivery technology which we are continuously demonstrating enables superior delivery of many compounds."

Release of the conclusions from this pre-clinical investigation coincides with Phosphagenics' two further clinical trials of its TPM® opioid pain patch technology for the systemic treatment and management of chronic pain using oxycodone and oxymorphone.

The combined US market for these two compounds, currently administered orally, exceeds 70 per cent of the \$5 billion extended-release opioid market.

While oxycodone dominates the market, sales of oxymorphone grew by over 17 per cent in 2012 to become the third largest opioid in the category.

## **Ends**

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### **About Phosphagenics**

Phosphagenics Limited is commercialising drug delivery applications based on its novel transdermal (drugs administered via skin) TPM® – Targeted Penetration Matrix technology. TPM® is a patient friendly and cost effective system used to deliver proven pharmaceutical and nutraceutical products.

The lead product advancing through clinical trials is an oxycodone matrix system for the relief of chronic pain.

Phosphagenics' shares are listed on the Australian Securities Exchange (POH) and its ADR – Level 1 program in the US is with The Bank of New York Mellon (PPGY).

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