



15 September 2009

## Company Announcement

### **PHOSPHAGENICS ANNOUNCES SUCCESSFUL COMPLETION OF ITS TRANSDERMAL OXYCODONE MATRIX PATCH PHASE 1 TRIAL**

- ***Oxycodone successfully delivered into the bloodstream in a reproducible and consistent manner***
- ***Single application of Phosphagenics' matrix patch technology demonstrated sustained release of pain drug***
- ***To date oxycodone can only be delivered orally or intravenously***
- ***The annual market for oxycodone – which has fewer side effects than its competitor in chronic pain relief, morphine – is US\$1.5 billion***

Phosphagenics Limited (“Phosphagenics”) (ASX: POH; OTCQX: PPGNY) today announced the successful completion of a Phase 1 clinical study of its patented oxycodone transdermal matrix patch system. The results of the trial established that after a single dose, the patch delivered oxycodone into the blood stream in a reproducible, consistent and sustained manner.

With sales exceeding \$US1.5 billion annually, oxycodone, an opioid derivative, is one of the world’s leading drugs for pain management. Although it is more potent than morphine, it produces less adverse side effects. Currently the drug can only be administered orally or intravenously. Phosphagenics aims to become the first company to offer chronic pain sufferers, such as cancer patients, an oxycodone gel or patch that will provide sustained pain relief.

The Phase 1 trial results showed that the patch delivered approximately 40 mg of oxycodone into the body over a 7-day period. Subjects were given a single dose of the drug using the company’s matrix patch which was removed three days after application. At this time point, the oxycodone plasma concentrations were still increasing, suggesting that they had not peaked at the time of patch removal. Significantly, oxycodone delivery into the blood continued for four days after the patch was removed, demonstrating the depot effect of the company’s patented carrier system within the skin.

The trial was designed to assess the absorption profile of oxycodone in a matrix patch following a single administration, to acquire information necessary to obtain ethics approval for the repeat dose study. This being the objective of the study, only one of the company’s proprietary patches was used. The upcoming repeat dose study will be conducted on both the matrix and reservoir patch systems to determine the best patch for the Phase 2 and 3 clinical trials.

The open label, single centre study was conducted at the Royal Adelaide Hospital under the guidance of Principal Investigator, Professor Guy Ludbrook, (Professor of Anaesthesia, University of Adelaide) who said, “These results are exciting. The profile of the oxycodone

patch appears potentially very suitable for chronic pain management. After a dose of oral oxycodone pain relief is provided for only a matter of hours. The use of Phosphagenics' oxycodone patch may provide sustained drug delivery for a matter of days, thus removing some of the peaks and troughs of pain relief associated with oral treatment. "

Dr Esra Ogru, Chief Operating Officer said, "The oxycodone Phase 1 trial was a very critical study for Phosphagenics demonstrating that our patch system could deliver oxycodone into the blood stream. The results are a world first and represent the potential of a significant breakthrough in the treatment of chronic pain. We are very excited to be developing a treatment regime that will lead to therapeutic pain reduction and provide clinicians with more flexibility for treating patients. Our next trial, scheduled to be completed before the end of this year will involve a repeat daily dosing study and will examine oxycodone blood levels over a longer period."

Dr Ogru added that "because all opioids have similar molecular structures, it is quite possible that a successful oxycodone program could be applied to many other opioids in a market whose sales exceed US\$6 billion annually. We are also in the final stages of submitting our US IND for our formulated oxycodone."

ENDS...

## **APPENDIX AND NOTES TO EDITORS**

### **About Phosphagenics Limited**

Phosphagenics is a Melbourne-based, globally driven biotechnology company focused on the discovery of new and cost effective ways to enhance the bioavailability, activity, safety and delivery of proven pharmaceutical and nutraceutical products. Phosphagenics' core technology is built around the science and application of phosphorylation, a process where the addition of a phosphate group has been found to enhance the bioavailability, activity and safety of existing pharmaceuticals and nutraceuticals, as well as to assist in the production of drug delivery platforms. Phosphagenics' shares are listed on the Australian Stock Exchange (POH) and its ADR – Level 1 program was established in the U.S. with The Bank of New York Mellon (PPGNY) for U.S. investors to trade in Phosphagenics' stock on the 'over-the-counter' market. In July 2007, this was upgraded to the International OTCQX, a new premium market tier in the U.S. for international exchange-listed companies, operated by Pink Sheets, LLC. For more information, please visit Phosphagenics' web site at [www.phosphagenics.com](http://www.phosphagenics.com).

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