



ASX Limited  
Market Announcements Office

## Oxymorphone Patch Program Update

- ***TPM<sup>®</sup>/Oxymorphone patch development and clinical program reviewed***

**14 May 2015, Melbourne:** Australian drug delivery company, Phosphagenics Limited (ASX: POH; OTCQX: PPGNY), has completed a review of its TPM<sup>®</sup>/Oxymorphone patch development program using specialist external consultants.

On the back of previously announced clinical trial results showing that the TPM<sup>®</sup>/Oxymorphone patch can deliver blood levels of oxymorphone corresponding to the therapeutic levels seen with oral dosing, a further three critical path non-clinical studies have now been completed. These studies assessed the “development and commercial readiness” of the patches made during the recently completed technical transfer process.

The review of these non-clinical trials has concluded that additional specialised formulation work will need to be completed before the patch can be progressed further in the clinic. The Company will engage an external group with expertise in patch development for this process.

This reformulation is expected to delay the lodgement of an IND and Phase 2 trial planned for the USA by more than 12 months.

Phosphagenics’ topical oxycodone patch is in Phase 2 clinical trials. The number of patients being dosed continues to grow each month and remains on track to complete the trial in 2H 2015.

### **ENDS**

### **Enquiries**

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## **About Phosphagenics**

Phosphagenics Limited is a drug delivery company that is commercialising various products within the pharmaceutical, cosmetics and animal health sectors, using its proprietary drug delivery system called TPM<sup>®</sup> (Targeted Penetration Matrix). TPM<sup>®</sup> is a patient friendly and cost effective system, based on Vitamin E, that enhances the topical or transdermal delivery of active molecules. The lead products advancing through clinical trials are oxymorphone and oxycodone patches 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 (PPGNY).

## **Inherent Risks of Investment in Biotechnology Companies**

There are a number of inherent risks associated with the development of pharmaceutical products to a marketable stage. The lengthy clinical trial process is designed to assess the safety and efficacy of a drug prior to commercialisation and a significant proportion of drugs fail one or both of these criteria. Other risks include uncertainty of patent protection and proprietary rights, whether patent applications and issued patents will offer adequate protection to enable product development, the obtaining of necessary drug regulatory authority approvals and difficulties caused by the rapid advancements in technology.

## **Forward-looking Statements**

Certain statements in this announcement may contain forward-looking statements regarding Company business and the therapeutic and commercial potential of its technologies and products in development. Any statement describing Company goals, expectations, intentions or beliefs is a forward-looking statement and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties, particularly those risks or uncertainties inherent in the process of developing technology and in the process of discovering, developing and commercialising drugs that can be proven to be safe and effective for use as human therapeutics, and in the endeavour of building a business around such products and services.

[www.phosphagenics.com](http://www.phosphagenics.com)