



PHOSPHAGENICS

ASX Limited  
Market Announcements Office

## Phosphagenics Opioid Patch Program Update

- ***Next phase of the TPM<sup>®</sup>/Oxymorphone clinical development program has commenced***
- ***TPM<sup>®</sup>/Oxycodone Phase 2a trial to be conducted in Australia during Q4/2014***
- ***TPM<sup>®</sup>/Oxymorphone Phase 2 trial to be conducted in the United States in H1/2015***

**28 July 2014, Melbourne:** Australian drug delivery company, Phosphagenics Limited (“the Company”) (ASX: POH, OTCQX: PPGNY), provides the following update on its opioid transdermal patch programs after its recent announcement of a \$19.2 million capital raising. This update is intended to provide clarity on how the Company will apply the newly raised funds to progress the development of its lead pharmaceutical assets.

Phosphagenics is developing two novel opioid products, a TPM<sup>®</sup>/Oxymorphone patch and a TPM<sup>®</sup>/Oxycodone patch. Today, both oxymorphone and oxycodone are available as oral extended release (“ER”) medications for the treatment of moderate to severe chronic pain in various global markets. Given the potential competitiveness between the two molecules in the pain market, the Company has consciously formulated the two products using its TPM<sup>®</sup> drug delivery platform to treat two related but distinct pain indications. The TPM<sup>®</sup>/Oxymorphone patch has been developed for systemic delivery and treatment of moderate to severe chronic pain, while the TPM<sup>®</sup>/Oxycodone patch is for localised topical delivery and treatment of peripheral neuropathic pain.

As the Company has previously reported, US sales in the extended release opioid market in 2013 were around US\$6 billion. Of this market, sales of transdermal patches accounted for \$1.4 billion (with sales of fentanyl accounting for over 90% with the balance being for buprenorphine); sales of oxycodone were \$2.9 billion and for oxymorphone around \$600 million. Coincidentally, the global market for peripheral neuropathic pain is also around \$6 billion annually with neuropathic back pain accounting for almost 50% of this market.

### **TPM<sup>®</sup>/Oxymorphone Patch**

Phosphagenics is pleased to announce that it is advancing its TPM<sup>®</sup>/Oxymorphone patch towards Phase 2 development. Previously, the Company reported positive results from two Phase 1 clinical trials, including a trial outcome in late 2013 that confirmed the transdermal delivery of therapeutic oxymorphone plasma concentrations, a very strong predictor of efficacy. Prior to Phase 2 initiation, the TPM<sup>®</sup>/Oxymorphone patch is being further characterised in two additional clinical

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studies. Data from both studies will support an investigational new drug (“IND”) application that will be submitted to the US Food and Drug Administration (“FDA”). Filing an IND is the regulatory step required in order to conduct a Phase 2 trial in the USA and the IND process will add significant value to the asset.

The first additional clinical trial is currently in progress and addresses supplementary pharmacokinetic parameters to those examined in the previous trials. The second clinical trial, which is anticipated to start in October 2014, will evaluate two standard investigational endpoints for transdermal products; the consistency of the delivery profile among several potential patch application sites (i.e. flank, chest, upper arm and upper back) and the rest period required before a patch can be reapplied to the same application site. Both parameters are important aspects of protocol design for the Phase 2 trial that will be conducted in the USA, as well as forming part of the eventual label claims of the commercial product.

Chief Executive Officer, Mr Harry Rosen, said that the results of these two additional studies are extremely important to the Company’s ongoing discussions with potential licensees, and that the clinical trials add considerable value to any commercial deal for the Company.

The strategic change in our clinical direction for the TPM<sup>®</sup>/Oxymorphone patch from a small Australian Phase 2a study to a much larger Phase 2 trial in the USA was announced in our March 2014 Newsletter to Shareholders. This change resulted from the exceptional results obtained in our multi-dose study in late 2013 and from extensive consultation with regulatory and commercial advisors following those results. This decision was also reflective of the early interest in the product from potential licensees and the need to accelerate the development of the product in the US, the primary market for the TPM<sup>®</sup>/Oxymorphone patch.

Since the decision has been made to advance the clinical studies to the USA, the Company has undertaken extensive work to ready itself for submitting an IND application to the USFDA needed prior to commencement of the US Phase 2 study in H1/2015.

Lee Simon MD, former head of the FDA’s division of Analgesic, Anti-inflammatory and Ophthalmologic Drug Products and a consultant to the Company said, “It is entirely appropriate that the clinical program is now progressed in the USA which is a key commercial target market for the opioid patch technology. A successful trial in the USA would add significant credibility to the already informative results announced from the Phase 1 trials.”

### **TPM<sup>®</sup>/Oxycodone Patch**

The Company is also advancing its TPM<sup>®</sup>/Oxycodone patch into Phase 2a development for the treatment of peripheral neuropathic pain. Previously, the Company has conducted several Phase 1 trials to optimise the transdermal technology. Now, the TPM<sup>®</sup>/Oxycodone patch is scheduled to re-enter the clinic in a Phase 2a study in Q4/2014, with ethics committee approval expected in October 2014. This single dose proof-of-concept trial will investigate the ability of the topical application of the TPM<sup>®</sup>/Oxycodone patch to provide pain relief for patients suffering from post-herpetic neuralgia (“PHN”), a peripheral neuropathic pain condition. The study will be conducted at a number of clinical sites in Australia. Although the Company expects to complete the trial in Q2/2015, this will depend entirely on patient recruitment rates.

The Phase 2a study will help establish whether localised delivery of an opioid can relieve pain in a peripheral neuropathic pain condition. This represents a completely novel therapeutic application for an opioid and would be a valuable addition to the suite of currently available medications which have limited efficacy. In addition to neuropathic pain, the Company also intends to investigate the application of the TPM<sup>®</sup>/Oxycodone patch to other chronic localised pain conditions such as osteoarthritis of the knee. Related to that, the Company's announcement in May 2014 that outlined the success of the veterinary counterpart of the TPM<sup>®</sup>/Oxycodone patch in providing pain relief to thoroughbred racehorses with shin pain provides some degree of confidence for human efficacy to non neuropathic pain indications. The targeting of additional indications will expand the product's market potential. Any additional clinical studies would be conducted in the USA under an IND.

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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.

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