



*ASX Limited  
Market Announcements Office*

## **Phosphagenics Licensing Agreement Update**

10 September 2018, Melbourne: Phosphagenics Limited (ASX: POH; OTCQX: PPGNY) has become aware that the Mylan worldwide US online product catalogue has been updated. It now includes a generic daptomycin injectable product (Daptomycin Product) and also shows a list of wholesalers for the Daptomycin Product.

Mylan Laboratories Limited (Mylan LL) received FDA approval to market a generic daptomycin injectable in the USA on 6 June 2018 under ANDA 205037. On 27 July 2018 Mylan LL's label was published on the US National Library of Medicine website identifying that the generic daptomycin product would be sold under a "Mylan" label.

Under the Licensing Agreement dated 26 October 2012 (originally signed with Agila Specialties Private Limited who were subsequently acquired by Mylan LL) (Licensing Agreement) Phosphagenics' TPM technology is licensed exclusively for the development and commercialisation of a TPM/daptomycin injectable product.

While Phosphagenics is not aware of whether any sales of the Daptomycin Product have been made, Phosphagenics considers that any such sales by Mylan LL or any related Mylan party would be restrained under the terms of the Licensing Agreement. Phosphagenics has accordingly reserved its rights.

Shareholders are advised that while this is again an issue related to the Licensing Agreement with Mylan LL, this is a matter entirely separate to the Singapore arbitration completed in November 2017 on which both parties presently await a decision.

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## **About Phosphagenics**

Phosphagenics Limited is focused on developing and commercialising innovative Human Health, Animal Health and Personal Care products using its proprietary drug delivery system called TPM<sup>®</sup> (Tocopheryl Phosphate Mixture). TPM<sup>®</sup> is derived from Vitamin E using a unique, proprietary and patented process and has been proven to enhance the solubility and oral, dermal and transdermal absorption of drugs and nutrients.

Amongst its major projects, Phosphagenics' is developing TPM<sup>®</sup> enhanced patches, gels and injectable products for the human health market and is also developing TPM<sup>®</sup> to enhance the feed efficiency and health of livestock.

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)