

ASX Limited
Market Announcements Office

# **Phosphagenics – Arbitration Award Issued**

12 November 2018, Melbourne: Australian drug delivery company, Phosphagenics Limited (ASX: POH; OTCQX: PPGNY), advises that the Singapore International Arbitration Centre (SIAC) issued its Partial Final Award at 12.24am on Saturday November 2018.

On 6 January 2016, Phosphagenics announced that it had commenced confidential arbitration proceedings against Mylan Laboratories Limited (Mylan), a wholly owned subsidiary of Mylan Incorporated, by filing notices of arbitration at the SIAC. In that announcement Phosphagenics advised that, in accordance with its continuous disclosure obligations, it would notify the market of any material events as and when they occur.

The Board is very disappointed to announce that Phosphagenics was unsuccessful in all of its claims.

The award includes findings against Phosphagenics' claims to intellectual property rights relating to a lyophilised TPM®-daptomycin formulation; and its claim that Mylan had not used commercially reasonable efforts to develop TPM®-daptomycin.

Notwithstanding the award the Licensing Agreement remains in force. The Licencing Agreement includes clauses requiring Mylan to continue to take commercially reasonable efforts to develop TPM®-daptomycin, not to sell a generic daptomycin (with limited exceptions) and to pay royalties to Phosphagencis on commercial sales of TPM®-daptomycin. Phosphagenics may be required to enforce its remaining rights to require Mylan to act in line with requirements of the Licencing Agreement.

The parties will make submissions on costs (on a date to be set) which are reserved to a final award on costs. Phosphagenics has spent approximately \$5.6m on arbitration and legal fees to date. The Board must take into account a significant adverse costs order.

As shareholders will recognize, this arbitration loss has a serious impact on the company and the Board will need to carefully consider the alternative courses of action available to it.

The company currently has cash on hand of \$2.3m, which does not take account of a further \$0.2m of R&D incentive refund expected before the end of the year.

#### **Enquiries**

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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® (Tocopheryl Phosphate Mixture). TPM® 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