

**ASX Limited  
Market Announcements Office**

## **AGM Chairman's Address and Presentation**

**22 May 2019, Melbourne:** Attached is the Chairman's address together with the Company presentation to the Annual General Meeting of Phosphagenics Limited (ASX: POH), to be held at 12:00pm (AEST) today.

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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> (Targeted Penetration Matrix). TPM<sup>®</sup> is derived from Vitamin E using a unique, proprietary and patented processes and has been proven to enhance the solubility and oral, dermal and transdermal absorption of drugs and nutrients.

Amongst its major projects, Phosphagenics is delivering 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).

### **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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#### **Phosphagenics Limited**

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# 22 May 2019

## Annual General Meeting

### Chairman's Address

Dear Shareholders,

I am pleased to welcome you to the Annual General Meeting of Phosphagenics.

Before we enter into the formal business of the meeting, I would like to spend a few minutes reflecting on the progress and events of the year, and also share my vision for the future of the company.

In 2018 the operational focus has been on the progression of our TPM portfolio – which I'll talk to in more detail shortly. However, as you know this work was performed against a backdrop of some uncertainty due to the delay in the arbitration outcome, and then ultimately the result itself.

There is no doubt that this was a disappointing outcome, and one that came as a surprise to us.

Following the arbitration outcome, we faced the possibility of a crippling cost claim against us and moved swiftly into negotiations with Mylan and with Strides - the company from which Mylan originally acquired the rights to TPM® Daptomycin. This outcome was critical to secure the future of the company – and was more positive than some had predicted -we were able to minimise the cost claim and provide certainty around the licensing agreements.

The outcome we agreed with Mylan and Strides includes the following:

- Mylan retained the IP and rights to develop, license, market and/or sell TPM®-Daptomycin and if so agreed it would pay POH a 5% royalty;
- POH received right to again develop, license, market and/or sell TPM®-Daptomycin and if so agreed it would pay Mylan a 5% royalty;
- All other agreements and rights under MRA or Licenses agreement were mutually foregone
- Strides agreed to a payment of 100,000 pounds, and in turn agreed to forego all other claims against POH, including cost;
- First right of refusal to all POH Human TPM® assets existing and not otherwise encumbered at signing of the agreement (deal to be negotiated in good faith);

- Discount on upfront, milestone and/or royalty up to the lesser of 5M pounds or actual cost of arbitration.

This was a positive result for Phosphagenics which minimised further financial liability, gave us back the rights to develop and commercialise TPM®-Daptomycin, and high potential of a further deal with Strides.

Amidst this backdrop, the company was able to progress on a number of fronts and deliver on its operational goals – under the able leadership of Dr Ross Murdoch, our former CEO and now non-executive Director, and with the support of Dr Paul Gavin our CSO and Dr Roksan Libinaki, General Manager. This team has delivered prudent cost management, which has resulted in us again reducing fixed costs while focusing on the value-creation activities of R&D and BD, across the portfolio.

## **Human Health**

Our major internal R&D focus remained on injectables which are simpler, quicker and less expensive to develop than patches. Candidate injectable drugs for reformulation with TPM® were disclosed in the non-confidential presentation released Q3 2018, and are included on slide above. These prototype formulations have successfully passed formulation stability studies, the first hurdle for a new formulation. We have now begun to present these reformulated products to injectable companies for feedback and expressions of interest in co-development.

The toxicology program designed to support the propofol injectable product continues. We are expecting these studies to conclude shortly, and a decision on the path forward to be made with Terumo.

With the conclusion of the arbitration, the daptomycin product has immediately become the company's most advanced asset, significantly strengthening the overall portfolio. The addition of TPM® has been shown to reduce the time required to dissolve the product while also increasing its chemical stability. Both of these attributes are seen as commercial advantages over the generic products. Generic daptomycin injectable brands without the benefit of TPM® are selling in excess of US\$450M/yr in the US alone. Much of the development work on the product has been completed. Phosphagenics has now prioritised the completion of the TPM® daptomycin product, with the aim of filing an NDA with the US FDA. The company is now discussing the cost and time to complete the remaining work with external service providers.

The opioid crisis has raised questions about the approvability of POH's opioid patches. In Q2 2018 POH submitted a request to get formal FDA feedback on the regulatory acceptance of its Oxymorphone patch. Specifically, POH had questions related to the clinical and non-clinical development plans, the requirements for abuse deterrent technologies and how the agency would perceive a new opioid product in the current environment. In December, POH was able to meet with the FDA, to discuss these issues. POH received an encouraging hearing from the agency, receiving positive feedback on the development plans required for approval and guidance on how to maximise the benefits of the product with respect to abuse potential and future product labelling. Importantly, the agency confirmed the approvability of the product, which opens the door for POH and/or a partner to develop the patches and expect a favorable hearing when requesting approval.

We continue to actively pursue partnership options across the Human Portfolio.

### **Animal Health and Nutrition**

Over the past three years the animal health team has produced a substantive body of positive data whilst keeping its resource requirement to a minimum. We have been able to undertake multiple trials across multiple species and produce data that can support the scientific and commercial justification for TPM® as a valuable additive for livestock.

The R&D efforts in 2018 were focused on:

- Finalising work substantiating TPM® as a valuable feed additive for pigs, poultry and cattle and support work undertaken by multiple potential partners (also added to the body of available data) including major trials undertaken as part of their due diligence activities.
- Preparing and progressing the TPM® dossier required for the regulatory approval process for its use as a livestock feed additive in Europe.
- Additionally a manuscript was recently accepted for publication into the Animal Feed Science & Technology Journal.

Business development focused on:

- Partnership discussions, with multiple suiters identified and engaged. Multiple global companies embarked on due diligence trials that progressed throughout 2018 and into 2019 and results have now been received. The results have either supported previous findings and/or extended the value add proposition – which is positive. And therefore partnership discussions, including initial terms, are ongoing.

## **Production**

Ashland remains our largest customer, with sales since the last AGM in excess of \$1.25M, with \$0.5M of these sales coming in the first four months of this year alone. This relationship continues to strengthen and we are in discussions exploring ways to maximise the value of Vital ET™ and the close relationship we have built for both companies.

We also continue to await the first launch of products from our existing partners in the personal care space – Pure Beauty Australia and Rodan + Fields.

Phosphagenics remains committed to its stated strategy to focus on its core human health business, and to monetise non-core business units while retaining intellectual property and rights to manufacture TPM® outside the partnered fields of use.

## **Outlook**

Our immediate goal is to complete the outstanding partnerships / deals that will enable us to further monetise assets and maximise the avenues for non-dilutive funding available to us.

Our vision is to establish ourselves as a self-sustainable human biotechnology company, with a reduced reliance on the need to raise capital through existing investors. We will use the TPM® portfolio to spring-board forward, as we explore new opportunities both inside and outside of the portfolio.

Before concluding, I would like to thank and acknowledge Dr Ross Murdoch, our outgoing CEO, for his contribution. Ross' vision focus and execution has been greatly valuable in getting the company to where it is today and laying the foundation for the business development activities now in play. In the face of many challenges, Ross' commitment to the company was unwavering and I thank him for his leadership over these past four plus years.

We support Ross' decision to leave to pursue another opportunity but thank him for remaining on the Board – and I think that is a strong signal of Ross' commitment and principles, and positive working relationship with the Board and Leadership team.

I would also like to thank our Board and Executive Leadership team, and the staff at Phosphagenics for their hard work and continued support – and of course, our shareholders.

I look forward to sharing positive developments and a bright future with you.



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

# 2019 Annual General Meeting Presentation

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



# Human Health Assets

TPM® Product	Development Status
<b>Daptomycin injection</b>	<ul style="list-style-type: none"><li>• Late Phase Asset returned after Mylan arbitration. Development Plans determined. BD initiated</li></ul>
<b>Propofol injection</b>	<ul style="list-style-type: none"><li>• Partnered: Toxicology program ongoing</li></ul>
<b>Vitamin K injection</b>	<ul style="list-style-type: none"><li>• Passed 6 month stability. BD active</li></ul>
<b>Clopidogrel injection</b>	<ul style="list-style-type: none"><li>• Passed 6 month stability. BD active</li></ul>
<b>Azithromycin injection</b>	<ul style="list-style-type: none"><li>• Passed 6 month stability. BD active</li></ul>
<b>Melphalan injection</b>	<ul style="list-style-type: none"><li>• Passed 6 month stability. BD active</li></ul>
<b>Tacrolimus injection</b>	<ul style="list-style-type: none"><li>• Stability study ongoing</li></ul>
<b>Diclofenac gel</b>	<ul style="list-style-type: none"><li>• Partnered: On market as Voveran TPM &amp; Instanac TPM (India)</li></ul>
<b>Oxymorphone patch</b>	<ul style="list-style-type: none"><li>• Positive FDA pre-IND December 18. BD active</li></ul>
<b>Oxycodone patch</b>	<ul style="list-style-type: none"><li>• Phase II asset. BD active</li></ul>
<b>Other</b>	<ul style="list-style-type: none"><li>• Not yet disclosed (includes external driven opportunities)</li></ul>



# Animal Health Assets

TPM® Product	Development Status
<b>Poultry Feed</b>	<ul style="list-style-type: none"><li>• Benefits demonstrated across 5 studies:<ul style="list-style-type: none"><li>• POH demonstrated feed efficiency increases across 2 studies</li><li>• Manuscript accepted in “Animal Feed Science and Technology”</li><li>• Third parties demonstrated positive results beyond feed efficiency in 3 additional poultry studies.</li></ul></li><li>• Partnering discussions ongoing</li></ul>
<b>Pig Starter Feed</b>	<ul style="list-style-type: none"><li>• POH showed feed efficiency improvements in newly weaned pigs</li><li>• Partnering discussions ongoing</li></ul>
<b>Veterinary</b>	<ul style="list-style-type: none"><li>• Registered product/s under development with third party</li></ul>

## Animal Health applications supported by submission to the European Food Safety Authority (EFSA)

- Dossier is currently under review by the regulator





# Production Business

TPM® Product	Partner	Field	Sales
<b>Vital ET</b>	<ul style="list-style-type: none"> <li>Ashland</li> </ul>	<ul style="list-style-type: none"> <li>Personal Care</li> </ul>	<ul style="list-style-type: none"> <li>~16T (~\$1.25M) since last AGM</li> <li>~6.5T (~\$0.5M) YTD</li> </ul>
<b>TPM</b>	<ul style="list-style-type: none"> <li>Themis</li> </ul>	<ul style="list-style-type: none"> <li>Pharmaceutical</li> </ul>	<ul style="list-style-type: none"> <li>~200kg</li> <li>70kg YTD</li> </ul>
<b>TPM</b>	<ul style="list-style-type: none"> <li>Rodan + Fields</li> <li>Pure Beauty Aus</li> </ul>	<ul style="list-style-type: none"> <li>Personal Care</li> </ul>	<ul style="list-style-type: none"> <li>Development supply batches</li> </ul>
<b>TPM</b>	<ul style="list-style-type: none"> <li>Undisclosed</li> </ul>	<ul style="list-style-type: none"> <li>Veterinary</li> </ul>	
<b>TPM</b>	<ul style="list-style-type: none"> <li>Undisclosed</li> <li>Undisclosed</li> <li>Undisclosed</li> </ul>	<ul style="list-style-type: none"> <li>Animal Health</li> </ul>	

**Production business supports both human and animal health pipeline**