Newsletter – August 2018

TPM® Drug Delivery Technology| Pharmaceuticals | Consumer Products | Animal Health

Key Points:

- **TPM® Oxymorphone Patch pre-IND, FDA face-to-face meeting confirmed for December '18.**
- **Injectable candidates continue to progress – development candidates on track for 2018 Tox**
- **Multiple companies undertaking due diligence on Animal Health Business.**
- **Strong Vital ET sales on forecast for 2018**
- **Independent research coverage rates POH a 'Buy' with target 8-9 cents share price**
- **Mylan Arbitration Outcome: still to come.**

Welcome to the 3rd shareholder update for 2018. This edition follows up on the updates provided to shareholders in March as a Newsletter and in May at the AGM. In this issue of the newsletter I will again look to expand on a number of key topics that have generated questions from shareholders over the past few months.

TPM®-Daptomycin: The Mylan Arbitration and Agreement

The Mylan Arbitration remains the topic of most attention for both shareholders and potential investors. Again, as with every release we make related to the ongoing Arbitration with Mylan, I will start by restating that the Arbitration detail is confidential and that we are restricted on the amount and type of information we can release. I would also like to remind you that there is no guarantee of a decision or award in favour of Phosphagenics.

It has now been nine months or so since the completion of the hearing in Singapore. When the Singapore International Arbitration Centre (SIAC) indicated that an update would be provided in June, it generate considerable hope of a rapid conclusion, however we have not as yet received an update. Understandably this has given rise to a considerable number of enquiries from shareholders. We appreciate the frustration felt by shareholders around this issue. We updated the market of the foreshadowed update during the week of June 4th, and we updated the market that we did not receive that update. We remain committed to providing information to shareholders as soon as possible and we remain hopeful that we will receive positive news - but this is all in the hands of the Arbitrator and the arbitration process. In accordance with listing rules, we will keep shareholders and the market informed of any material matters as they arise.

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I would also like shareholders to again note that the that the ongoing existence of the Licensing Agreement between our company and Mylan Laboratories Limited will not be impacted by the arbitration outcome and will continue to be in force. Our company therefore continues to work within, and actively protect our rights under, the Licensing Agreement.

The TPM®-Opioid patch programs

Significant progress has been made in moving the globally applicable 3-day TPM®/Oxymorphone patch forward over the past months. Most notably is the recent confirmation from the FDA of a face-to-face Pre-IND meeting in Washington DC in December. The FDA preference was to meet to discuss the product rather than provide a response via written responses or teleconference (as originally offered by Phosphagenics). We believe that this is positive and highlights the FDA's interest in opioids and next generation products such as a TPM®/Oxymorphone patch. Discussions with the FDA are seen as essential to ensure a full understanding of the requirements for the US and global market. Work over the next months will focus on strengthening the detailed pre-meeting package required by the FDA in early November.

We expect the TPM®/Oxycodone patch program will also benefit from the FDA Pre-IND discussions focussed on the TPM®/Oxymorphone patch. Many of the development and approval questions are shared and it is hoped that these discussions will help clarify the requirements for approval of future opioid products such as our patches.

Progress in Growing an impressive Injectables Portfolio

For many years, Phosphagenics has focussed TPM® on dermal and transdermal routes of drug administration. Whilst this has provided us with legacy products now partnered and the opioid patches now entering pre-IND discussions, our path forward is different, it lies heavily with our commitment to TPM® and injectable products. We are beginning to prove that this can be a rapidly growing part of our pipeline into the future.

Our R&D team continues to make significant progress in developing new injectable formulations that have:

- replaced toxic or problematic excipients such as Cremophor EL or lecithin,
- enhanced the solubility of relatively insoluble drugs,
- improved the stability and usability characteristics of existing commercial drugs,
- lessened the potential to harbour bacterial contamination or physical impurities, and
- altered the dosage form i.e.: making formulations reliant on lyophilisation into stable liquids

In May this year shareholders were made aware of the names of the initial cohort of TPM® injectable targets. These were released as part of both my AGM address and the updated non-confidential corporate presentation used in a new round of corporate roadshows (see Appendix 1). The first cohort is now progressing through different stages of formulation and stability testing. This involves the generation of large numbers of formulations in a matrix style design to examine the effect of a range of formulation variables. These variables include the addition and concentration of various formulation ingredients (including TPM®, co-solvents, and/or other excipients), the physical form of the formulation (solution, micro emulsion or vesicular suspension) and the formulation pH. Formulations are stressed using cycles of alternating hot and cold in order to identify which variables increase of decrease stability. The results of these studies provide direction for further reformulation in order to optimise a formulation with the desired attributes. The goal is to identify one (or more) formulation(s) with the characteristics required to:

- provide at least 2 years of shelf-life stability and
- fit a predetermined commercially superior "target product profile".

The number of different variants and optimisation steps needed, and ultimately the time required to develop a suitable candidate vary widely depending on the chemical and structural characteristics of the target. Having said this, I am pleased to announce that we have formulations across several target molecules that demonstrate the appropriate stability characteristics to be prioritised as development candidates. This is good news not only related to the single target but also because with each success we build a more comprehensive picture characterising the "do's and don'ts" of TPM® formulations – hopefully guiding and accelerating our work on the next round of targets. Plans to progress prioritised candidates into formal toxicology studies are being evaluated and will form separate announcements when toxicology studies initiate.

While I am sure you are encouraged by the progress and successes to date, I want shareholders to know that these successes are in no way just "plug and play" – the progress to date has been the result of considerable invention and multiple rounds of testing and retesting. We are now considering the next cohort of 6 or so new targets.

The most prominent example of TPM®'s utility at present remains TPM®/daptomycin (the subject of the arbitration) and TPM®/Propofol where we have been able to develop a clear formulation to replace the commercially available but sub-optimal milky opaque emulsion. The latter has already moved into the formal development process although progress has been slower than we had hoped: we expect that this can be accelerated.

The Terumo Partnership

In 2016 Phosphagenics and Terumo entered an agreement allowing for the development of up to four parallel projects utilising TPM®. In my last Newsletter I emphasised how useful this has been in providing additional expertise and millions of dollars to projects associated with this R&D alliance – most notably with our opioid patches and TPM® injectables. A number of novel concepts outside of patches and injectables have been investigated including gels and sprays. One example is a topical pain relieving TPM®-ropivacaine gel which was created under the agreement but ultimately not taken to license by Terumo. In line with the contract, this is now the property of Phosphagenics' alone and available for license. The TPM®/ropivacaine gel project attracted R&D reimbursement from Terumo who also paid an additional $250k milestone fee at the conclusion of the project.

Moving forward: The return of the TPM®/Oxymorphone patch in early 2018 (due to Japanese specific market concerns) has promoted the co-developed TPM®/Propofol injectable to flagship position in this relationship. The development of a TPM®/Propofol injection had unique challenges – none less than the need for the formulation to support acute injection as well as 24hr infusion. This is the first time that this TPM® based injectable formulation (or in fact TPM® alone) will be tested at such high dose over such a long exposure period in formal toxicology studies. Formulation design and agreement on the exact test protocols have lengthened the program and extended the toxicology program timeline. However, we believe that a suitable program is now designed and the testing pathway can now continue.

Ensuring the right toxicological program for TPM®/Propofol injectable formulation is important as it potentially has wide reaching implications for all of the TPM® injectable program. It is expected that positive results will provide data that can support and potentially reduce the toxicological testing requirements of all future TPM® injectables. We also believe that these results will play a role in the direction that Terumo decides to take this relationship in the future. Discussions with Terumo over potential injectable projects continue.

Progress within the Animal Health Business

The initial Animal Nutrition R&D program, devised and initiated over 2 years ago, to demonstrate TPM® utility in livestock is now complete. Promising data in two poultry trials showing significant benefits of TPM® under normal and heat stress conditions combined with positive results in newly weaned pigs, and the potential in cattle have attracted a number of potential suitors for partnership and licensing. Work in 2018 has focussed on moving forward regulatory applications for TPM® in Animal Feed and servicing the business development activities needed to optimise the potential for partnerships. Discussions with a number of potential partners are ongoing and several have initiated due diligence activities, including trials of their own. Work remains on track and we hope to be able to provide shareholders with updates in 2018.

The Relaunch and Strengthening Orders of Vital ET® from our Global Partner Ashland

We have previously eluded to the positive results our partner Ashland has achieved with the relaunch of Vital ET®. Early in 2017 Ashland forecasted upward of 14 tonnes of demand over 2018. This forecast has been now converted into firm purchase orders and the first half delivered on schedule. Forecasts for 2019 are now being formulated.

Positive NDF Research report: *"…Rating '**Buy**'…Target Price **8-9 cents**…"*

Well researched, comprehensive research coverage and analysis by a reputable independent analyst is a powerful tool both for the company and for potential investors. Large companies can typically rely on investment banks and broking houses to provide this to the market as part of their service to clients. The research coverage provides investors and the market with the detailed analysis of a company's potential they want and need, but don't have the time or personnel to generate themselves. For small Australian biotechnology companies like Phosphagenics however, this is typically not available and detailed research coverage and analysis needs to be commissioned. Understanding this, we commissioned Mr Stuart Roberts of the independent research firm NDF Research based in Sydney to prepare an independent research report on Phosphagenics. Mr Roberts has been a respected life sciences sell-side analyst since 2002 as well as being an executive of 2 ASX-listed immune-oncology drug companies.

I don't intend to rehash the report here as it is available for all shareholders to read on www.ndfresearch.com and also can be accessed through Phosphagenics website in www.phosphagenics.com. I would however like to highlight that Mr Roberts developed a number of business cases for Phosphagenics concluding that its present assets and opportunities provide for a potential valuation range, based on assumptions set out in the report, of approximately 6 to 12 cents per share with a target of around 8-9 cents per share (a five-fold increase on the present share price). He rated the stock as a "buy". He also noted a number of potential events in the relatively short term that could drive this re-rating of the stock. The report is thorough and informative and urge all shareholders to read it.

CEO Quarterly Update Teleconference

There will be no follow-up shareholder teleconference associated with this Quarterly update due to overseas travel commitments associated with broker, investor and potential business development meetings.

Dr Ross Murdoch
CEO & Managing Director

Appendix 1.