

Newsletter – March 2018



Welcome to the first edition of our shareholder newsletter for 2018. In this issue of the newsletter I would like to expand on a number of key topics that have generated questions from shareholders over the past few months.

The Mylan Arbitration

The Mylan Arbitration is by far the topic that has attracted the most attention from both shareholders and potential investors. It has now been just over four months since the hearing in Singapore completed.

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 very 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.

The formal Hearing commenced on Monday, 23 October 2017 and concluded on Friday, 3 November 2017 and primarily involved cross-examination of Phosphagenics' "fact" and "expert" witnesses by Mylan's counsel and cross-examination of Mylan's corresponding witnesses by Mr John Rowlands (QC) and Ms Claire Cunliffe (Phosphagenics' counsel). Mr Rowlands and Ms Cunliffe were ably supported in the proceedings by a partner and two additional lawyers from Corrs Chambers Westgarth. The cross-examination period lasted eight full days with the final day (Friday 3 November) dedicated to closing arguments. The proceedings were formally closed on 13 December 2017.

While preparation for the Arbitration Hearing went very well and the Board and I were impressed with the preparation and performance by our legal team, it is not possible to predict the outcome or the timing for a decision - both remain solely at the discretion of the Arbitrator and SIAC (the Singapore International Arbitration Committee). Having said that, the Board and I remain confident in the merits of the decision to take this action on behalf of shareholders. Expenses associated with the Arbitration have now been fully included in the 2016/2017 financial accounts and the expectation remains that a decision is likely occur within the first half of 2018.

We will keep shareholders and the market informed of any material matters that arise.

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The Terumo Partnership

In 2016 Phosphagenics and Terumo entered an agreement allowing for the development of up to four parallel projects utilising TPM®. Since signing over AUD \$2.5 million has been invested into projects associated with this R&D alliance. Projects that have been evaluated include the TPM®/Oxycodone patch, the TPM®/Oxymorphone patch, the TPM®/Propofol injectable and a number of other novel concepts including gels and sprays. The agreement allows for shared R&D responsibilities, territories and revenues. We have already collaborated on a number of concepts including:

- a novel clear TPM®/ Propofol injectable now protected by a new provisional patent application and entering preclinical development;
- a Japanese specific TPM®/Oxymorphone patch, and
- multiple prototype formulations for novel TPM® products primarily targeting pain – those not taken up for further development become available for global licensing by Phosphagenics.

In 2017 Terumo signed a separate term sheet specifically addressing the development of a 1-day TPM®/Oxymorphone patch for the Japanese market including the exclusive right to move forward to a full license agreement. Terumo specified requirements that included high dermal delivery, a single day design and a size that could directly compete with the highly potent fentanyl patch already approved in Japan. The resultant TPM®/Oxymorphone patch program has progressed well, resulting in multiple new patch formulations that are more robust and higher performing than our original prototype, however none have been able to match all of Terumo's specific criteria – in particular the desired size. As announced separately, both companies have now come to the pragmatic conclusion that production of a patch that satisfies all of Terumo's specific requirements is unlikely within a mutually acceptable timeframe. Terumo has therefore terminated the development agreement associated with the development of a 1-day TPM®/Oxymorphone patch specifically designed for the Japanese market and returned all rights associated with the TPM®/Oxymorphone patch program to Phosphagenics. Terumo has also agreed to reimburse Phosphagenics for all outstanding costs associated with the program to date. Phosphagenics will now focus on advancing a more globally applicable 3-day patch project. The positioning and size requirements of a TPM®/Oxymorphone patch outside of Japan is expected to be different to that targeted by Terumo.

Terumo's management have emphasised that that this decision does not diminish their commitment to the TPM® technology, TPM®/Propofol or their partnership with Phosphagenics and they are very interested in investigating Phosphagenics' growing portfolio of early stage TPM®-based injectables for replacement projects. Discussions with Terumo over potential injectable projects have begun and we will keep shareholders and the market informed as discussions progress.

The TPM-Opioid Patch Programs

The TPM®/Oxymorphone patch program will now focus on progression of a new, more globally applicable 3-day patch and securing a global partner to continue progress into the clinic. Discussions with the FDA are seen as essential to ensure a full understanding of the requirements for the USA and global market, and plans to initiate discussion for progression of this patch into an IND are being formulated.

The TPM®/Oxycodone patch program has positively benefited from the visibility of Terumo's investments and we have seen recent renewed interest from other potential partners. Some limited internal R&D trialling has recently been undertaken to strengthen the data set available for these partners.

Our Growing Focus on Injectables

With the Company's most talked about Human Health assets continuing to be the two TPM[®] enhanced opioid patch products, it is easy for our expanding focus on TPM[®]'s enhanced injectable formulations to get less airtime than it deserves. As early as the AGM in May 2015, I indicated to shareholders that Phosphagenics would start to move focus towards injectables and this vision has begun to return significant value. Dr Paul Gavin provided an update of our rationale and goals for the injectable program as part of a previous newsletter and our scientists have made significant progress since then in developing new TPM[®] injectable formulations that can:

- lessen the need to use problematic and toxic excipients such as Cremophor EL and lecithin,
- enhance the solubility of relatively insoluble drugs,
- improve the stability and usability characteristics of existing commercially successful drugs,
- have less potential to harbour bacterial contamination or physical impurities.

We are moving forward with developing products focussed on each of these areas and are expecting a number of our leads to mature into development candidates over 2018. The most prominent example of TPM[®]'s utility at present are obviously TPM[®]/Daptomycin (the subject of the arbitration having been discussed earlier) and TPM[®]/Propofol where we have been able to develop a clear formulation to replace the commercially available but sub-optimal milky opaque emulsion - but these are just the beginning. We are committed to this path and expect this to be a growing part of our pipeline into the future.

Progress within the Animal Health Business

Two trials completed showing significant benefits of TPM[®] in Poultry: The Global Poultry Feed Market in 2016 was estimated to be worth over USD \$2.6 billion and is predicted to reach USD \$3.46 billion by 2021. For poultry to be healthy, they must get adequate protein, carbohydrates, vitamins and minerals from their feed and adequate amounts of water. TPM[®] is added to poultry feed to increase the absorption of vitamins and minerals, making it more efficient and cost effective. The poultry industry is very sensitive and receptive to even small improvements in feed efficiency and the results have caught the interest of research groups and leaders across the global feed industry.

The first of Phosphagenics' studies of TPM[®] in poultry demonstrated that 10ppm of TPM[®] added to standard broiler feed significantly improved growth rate and feed efficiency. Enhance nutrient uptake is believed of particularly benefit in times of stress. In line with this, the research facility that conducted the successful first study asked to assess TPM[®]'s potential benefits in their heat stress model. Heat stress can be a major problem for the poultry industry and has been shown in the past to significantly reduce growth and feed efficiency.

The results from this second study reinforced the findings of previous "normal temperature" studies and demonstrated that 10ppm of TPM[®] protected the birds from the negative effect of heat stress. In fact the growth rate and feed efficiency of the TPM[®] fed "heat stressed" birds were "normalised" and not different from the controls that were not heat stressed. The two studies combined make a compelling case for potential partners and presently a number of key global players in the animal feed industry are initiating due diligence activities.

Completion of the one year Dairy Cattle Study: The Global Cattle Feed and Feed Additive Market is very large and anticipated to grow from USD \$31.3 billion in 2017 to \$34.2 billion by 2022. Previous studies demonstrated that TPM[®] in an oral drench could be very useful in dairy cattle; successfully improving milk quality (i.e. somatic cell count reductions) and benefiting cows with sub-clinical and clinical mastitis. While oral drenches are used extensively across the dairy industry, pelleted feed formulations are considered far more commercially attractive. Phosphagenics therefore conducted a large, randomised, placebo-controlled study to assess if TPM[®] in pelleted dairy feed could provide the

benefits previously seen with TPM® in oral drenches. The study was conducted at two large commercial dairy farms in Victoria and monitored by independent dairy consultants.

Despite successful outcomes in monogastric (single stomach) species (i.e. pigs and poultry) functional differences between monogastric and ruminant species have reduced responses in the past. Oral drenches by-pass the first three stomachs of the cow directly entering the final stomach, changing the cow's gastric pathway to more closely resemble a monogastrics such as pigs and poultry. Pelleted feed is exposed to the full fermentation process and four stomachs of the cow, potentially lowering the effective dose of any ingredients including TPM®. Unfortunately in this study TPM® (in pelleted feed) did not replicate the successful outcomes seen with the oral drench or that seen in monogastrics indicating that more work is required to optimise the dose and delivery of TPM® in products for ruminants. This has been the focus of discussions with potential partners interested in the ruminant market.

Discussions with a number of potential partners are ongoing and several have initiated due diligence activities. We expect to be able to provide shareholders with updates as 2018 progress.

TPM®/Diclofenac Gel and China

In September last year Phosphagenics announced the signing of a term sheet with Sichuan Credit Pharmaceutical Co. Ltd (Credit Pharma) outlining a proposed development and licensing agreement granting Credit Pharma exclusive rights to develop, market and sell the TPM®/Diclofenac gel in China, Hong Kong, Macau and Taiwan. Phosphagenics received USD \$100,000 on signing the Term Sheet which provided Credit Pharma with a period of exclusivity to negotiate a definitive agreement and obligated Credit Pharma to pay a further USD \$300,000 to Phosphagenics on the signing of any definitive agreement. After considerable negotiation it has been determined that a full agreement that satisfies both party's interests will not be reached. Although no definitive agreement will be signed, Phosphagenics retains the USD \$100,000 and is now free to pursue other partners for the TPM®/Diclofenac gel in China.

The Entitlement Offer (Rights Issue)

Phosphagenics undertook a "Rights Issue" (1 for 4 offer at 1.5 cents per share) late last year with an initial target of greater than AUD \$3M. In total we raised AUD \$4.73M. I would like to extend my thanks and those of the Board of Directors for the strong show of support by our existing shareholders and those (now) new shareholders who underwrote the offer.

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

As highlighted in our recently released preliminary financial accounts, the Production and Personal Care business generated revenues in 2017 that were lower than those of the prior comparable period in 2016.

Despite our global distributor Ashland reporting commercial sales of Vital ET® growing in 2017, orders for new stock from Phosphagenics were disappointing as Ashland worked through the excess stock they had purchased in prior years. I am pleased to say that as of the end of 2017, this excess stock has been exhausted and strong orders have recommenced. Ashland informs us that enthusiasm for the product in the market place remains strong and a product relaunch in the second half of 2017 appears to have succeeded in encouraging existing customers as well as developing new customer partnerships. This has already resulted in Ashland's forecast and confirmed orders for 2018 exceeding those for 2016 and 2017 combined, amounting to over 14 tonnes (14,000kg). Vital ET is already in over 100 brands used world-wide and we believe that the recent increase in sales bodes well for its use to expand.

Summary Table

Human Health

TPM®-Gel	Diclofenac	20 markets licensed through Themis/Novartis.
TPM®-Patches	Oxycodone	Recent increase in business development activity.
	Oxymorphone	Terumo “Japan only 1-day patch” project discontinued -replacement injectable under discussion. “Ex-Japan 3-day patch” improved versions progressing; FDA feed-back targeted 2H ’18.
TPM®-Injectables	Daptomycin	Awaiting Arbitration outcome – four months since hearing; Mylan contract remains in place
	Propofol	Terumo/POH partnership - Joint provisional patent; 6m stability achieved; in preclinical toxicology phase
	“Yet to be disclosed”	Internal programs progressing well; multiple streams pursued with promising leads across multiple target areas; lead(s) selection targeted 2H’18 Terumo investigating potential additional injectable programs.

Animal Health & Nutrition

Non-Registered	Poultry	Benefits proven in Broilers in normal and heat stressed conditions. Multiple companies entered Due Diligence testing
	Pigs	Improved FCR in weaner pigs
	Dairy	1 yr trial complete; Primary endpoint not proven – TPM® decrease in mastitis events demonstrated

Production/Personal Care

Manufacturing	Vital ET®	Relaunch by Ashland has increased demand; 2018 orders forecast to exceed volume for last 2 years.
Personal Care		Product development by Rodan + Fields and Pure Beauty Australia advancing

CEO Quarterly Update Teleconference

Interested parties are invited to participate in a teleconference.

Date: Thursday, 22 March 2018

Time: 8:30 am AEST

Further dial-in details to follow in a separate announcement.



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