Phosphagenics

news

JULY 2016

Welcome to the fourth instalment of the Phosphagenics shareholder newsletter. Our last shareholder update was provided in conjunction with our Annual General Meeting in May, where I provided shareholders with an overall update on the business, either in person (for those able to attend) or via the associated ASX release. I intend to provide shareholder updates and Newsletters on a regular basis (typically quarterly). The next shareholder update should be in line with our regular quarterly update schedule towards the end of October.

Since the last newsletter, I am pleased to report the business has really delivered increased value through new partnerships and clinical progress:

- The Company signed multiple agreements with a leading Japanese company. At the time of signing it was not possible to provide the name of the company to the Market but we are now pleased to announce that it is "Terumo Corporation", a leading Japanese healthcare company with a rapidly growing footprint in the international healthcare space. These agreements cover the options to license the TPM®/Oxymorphone and TPM®/Oxycodone patch, plus an R&D alliance for up to four other TPM® based products.
- We expanded the existing license with Themis Medicare Limited for its TPM®/Diclofenac gel, to include an additional 16 geographical markets.
- In Animal Health we reported the results of a second pig study - this time in grower/finisher pigs - designed to assess the commercial value of TPM® as a feed additive in the pig production market.
- We also launched a study in dairy cattle, a separate long-term study to assess the potential for TPM® to enhance milk quality and conception rates in dairy cattle; targeted for completion during the final quarter of 2017.

I have highlighted on multiple occasions that my business strategy for Phosphagenics is to:

a) **assess:** assess the portfolio, people and growth opportunity;
b) **refine:** streamline the Company and resources to focus on the most valuable products and technologies with the highest likelihood of commercialisation; and
c) **partner and commercialise:** actively seek and productively approach potential collaboration partners (both existing and new) so as to accelerate and optimise the future development of existing and new TPM® based assets as well as facilitate non-organic growth.

The milestones achieved within the Human Health business over the past few months prove our ability to execute the third phase of this process. I believe that our ability to achieve agreements with two international healthcare companies provides positive validation of our technology and strategic approach.

Partnerships, such as those signed since our last update, are valuable to Phosphagenics and Phosphagenics' shareholders for multiple reasons: potential upfront/milestone payments; external non-dilutive funding of project R&D; reduced drain on our cash reserves; and access to external expertise. Most importantly, these partnerships provide confirmation and validation that our technology and our assets are attractive to large biotechnology and pharmaceutical companies.

I believe that no matter how strong a company's primary technology is, an essential second component of any "**partner and commercialise"** strategy (as I mentioned at the AGM) involves the assessment of external "non-organic growth" opportunities that can be brought in by way of in-licensing, merger and acquisition. We continue to assess opportunities on a regular basis. Our targeted systematic approach gives us a clear criteria to evaluate opportunities that can deliver improved and sustainable growth for Phosphagenics. We continue to seek out these opportunities, especially as the Company's TPM® assets progress through development and are partnered.

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We have also continued to investigate areas in the animal health and nutrition market where we believe TPM® has a strong likelihood of commercialisation. We are focused on two distinct opportunities: (i) the ability of TPM® to improve feed utilisation (as measured by "feed conversion ratio" or FCR) and (ii) the ability of TPM® to improve milk quality and fertility in dairy cattle. The first of our Animal Health studies reported earlier this year demonstrate that TPM® treatment could statistically improve FCR in young pigs. Our second study, where treatment was isolated to older (grower/finisher) pigs, indicated that they did not seem to benefit from treatment with TPM® (at doses 5 to 30 ppm) in the same way. Together these studies appear to support the concept that TPM® as a feed additive can potentially promote better wellbeing and growth, but the benefits may be more noticeable in younger or smaller animals. The next study is planned in poultry (broilers) and is expected to commence in the second half of 2016.

In parallel, during the second quarter of this year, we also initiated a study to investigate the potential of TPM® to improve milk quality and fertility in dairy cattle. The success of this study relies on a different value proposition to the FCR studies being undertaken in pigs and poultry.

Recently I have received a number of notes from shareholders anxious to hear updates on our ongoing legal matters; the ProPhase and Mylan arbitrations. As reported in our last update, the formal hearings in this arbitration were completed in the first quarter of 2016, with a decision expected within three to six months. We are now obviously nearing the end of that window and are hopeful for an imminent decision – although the timing of delivery is entirely at the discretion of the Arbitrator. We will provide shareholders with an update as soon as there is news to report.

Our arbitration against Mylan, in relation to TPM®/Daptomycin continues to progress. We asserted in our arbitration notices that Mylan/Agila Specialties breached several provisions under our agreements. Despite the arbitration proceedings, Phosphagenics' existing commercial agreement with Mylan remains in full force and effect pending the Arbitrator's decision. We remain confident that Phosphagenics has a strong claim and a favourable outcome should deliver a financial benefit in the form of a damages payment, in addition to the revenues that may flow to Phosphagenics from the existing agreement.

Phosphagenics' full year accounts were released at the end of February 2016 and showed revenue of $2.19m (2014: $2.05m). The Company reported a net loss after tax of $20.12m (2014: $8.94m) which included a $7.84m impairment to the value of intangible assets. The cash position as at 31 December 2015 was $12.40m (2014: $20.68m). In addition to this, Phosphagenics received $2.4 million associated with the R&D tax rebate on 29 March 2016. An additional R&D tax rebate will be submitted in Q4 2016.

Phosphagenics' half year accounts will be released in August 2016.

Our active portfolio of businesses and products now includes:

Human Health:

• TPM®/Diclofenac Gel	**Commercialised** (partnership expanded from 1 to 17 countries)
• TPM®/Oxycodone Patch	Phase 2a trial results announced - **Japan Partnership** option signed
• TPM®/Oxymorphone Patch	Reformulation ongoing - **Japan Partnership** option signed
• TPM®/Daptomycin Injectable	**Partnered** (late phase development/Arbitration pending)
• TPM®/Tretinoin Gel	Partner being sought
• TPM®/Propofol Injectable	**Partnered**, Global
• TPM®/other delivery forms	New candidates **partnered**, others under investigation

Animal Health & Nutrition:

• TPM® Pig Feed efficiency	Weaner + grower/finisher studies **completed and reported**
• TPM® Dairy Cattle Mastitis treatment	Study **initiated** (1st site) 2Q 2016
• TPM® Poultry Feed efficiency	Trialling to initiate in 2H 2016

Production & Personal Care:

• Vital ET®	**Commercialised** and partner relaunch planning underway
• TPM® non-GMP	**Commercialised** - Production efficiency and margin improved
• BioElixia® Brand	Negotiation for purchase ongoing *(subject to arbitration)*

HUMAN HEALTH
Dr Ross Murdoch & Dr Paul Gavin

Over the past 12 -18 months we focused on developing data packages suitable to support and expand partnerships around our key assets. In the past 6 - 9 months, we worked to use this data to build relationships, and over the past quarter or so we have observed the fruits of this effort.

In this quarter we have made significant progress in building and expanding business relationships within the Human Health business. We announced two partnership agreements with one of Japan's largest healthcare companies, Terumo Corporation, covering several of Phosphagenics' existing and new products. Terumo is a leading Japanese healthcare company with a rapidly growing footprint in the international pharmaceutical space. Within these agreements are two different types of partnerships: (i) option agreements for both our opioid patches and (ii) R&D alliance agreements covering multiple other TPM® -based (non-patch) assets.

Under the terms of the "Option Agreements -"Phosphagenics has received about $200,000 in the form of upfront option payments to maintain 6-month exclusivity and sponsorship of a US-based Scientific Advisory Board on opioids. Terumo will also conduct additional market research to confirm the development path and commercial opportunity for the products in Japan. If either or both options are exercised, and the companies enter into an exclusive license agreement, Phosphagenics expects to receive a licensing fee, payments upon the achievement of certain milestones, and royalties on commercial sales of the TPM®/opioid patches in Japan.

As part of the "R&D Alliance Agreement", the companies have agreed to collaborate on the global development of three additional pharmaceutical products leveraging Phosphagenics' proprietary TPM® technology, for the treatment of pain. Under the terms of this agreement, the two companies will jointly conduct an initial development program of about 24 months.

Terumo will lead and fully finance the development of our TPM®/Propofol injectable, building on the prototype already developed at Phosphagenics. Phosphagenics will lead the development of two additional novel TPM®-containing pharmaceutical products. Terumo will pay for all development costs, which are anticipated to be in excess of $1 million for the full 24-month period. In addition, upon the meeting of certain pre-defined success criteria, Phosphagenics would be entitled to success fees up to $1.5 million.

Upon meeting these success criteria, the two companies will also have the option to enter into a global development and licensing agreement for each of the three products. This agreement already establishes that Phosphagenics would retain marketing rights to Australia and New Zealand, Terumo would retain marketing rights to Japan, and the companies would equally share in all licensing fees and revenues gained from commercialisation of these three products in the rest of the world.

The option agreement with the TPM®/Oxycodone patch is particularly pleasing as it reinforces the message we provided to you in our last shareholder update: that the PHN study announced earlier this year not meeting its primary endpoint did not deter potential partners and that the strong positives associated with the patches' performance and the encouraging result from the 'post-hoc subpopulation analysis' continue to position it as a valuable and attractive opportunity to potential partners. We are jointly investigating options for a second study to build further efficacy data for this patch.

In support of the option agreement with the TPM®/Oxymorphone patch, the reformulation program with Tesa Labtec continues to progress well with the formulation of up to three new TPM®/ Oxymorphone patch candidates on-track to go into stability testing in 3Q 2016.

As we mentioned in the last update, the advantages that TPM® has added to daptomycin encouraged the Human Health business to move forward and investigate a number of other injectable candidates. This work is progressing well and has now gained further momentum with the recent announcement of the R&D alliance with Terumo around the development of a TPM®/Propofol injectable formulation. Formulation feasibility work on a number of potential candidates is ongoing.

We were also very pleased to announce that our Indian partner Themis Medicare will expand their license with TPM®/Diclofenac gel from 1 country (India) to 17 countries. In addition to a one-time payment of USD $30,000 for exclusivity to these territories, Phosphagenics will also receive a double-digit royalty on net sales of the product in addition to increased sales of TPM® for inclusion into the product. In addition, Themis has also modified its agreement with Novartis India from exclusive to non-exclusive allowing for Themis to potentially expand to other partners inside India itself. All this bodes well for Phosphagenics' future potential royalty revenue and also increased revenue from the direct sales of TPM® itself.

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Building on the momentum of our recent partnering successes, our Human Health Business Development is focused on delivering further value in the following four key areas:

- Further expanding the opportunity for TPM®/Diclofenac gel. With the current data set available, our main targets for quick regulatory approval and launch are additional emerging markets, including Russia, as well as other parts of Eastern Europe, Asia, Africa, and Latin America.
- Developing partnerships (similar to those now found for the pain portfolio) to support other indications such as dermatology, the other key opportunity for TPM®.
- Expanding our partnerships around TPM®/injectable products (we already have two global agreements - TPM®/Daptomycin and TPM®/Propofol), we will be looking for further partnerships to leverage TPM® in the injectable space.
- Finally, as alluded to above, we also continue to look for additional external "non-organic growth" opportunities that can be brought in by way of in-licensing, merger and acquisition.

We are pleased to say that our publication strategy is on track and progressing well.

This too has benefited from our focus on reviewing all data, assessing what gaps need to be filled and preparing for partners. Although the actual process to publication can be long, since May 2015, we have submitted five manuscripts for publication, one of which has been published in the *Journal of Pharmaceutical Sciences*, one is in the last phase of acceptance for publishing in *Drug Delivery and Translational Research* and a further three have been submitted and are awaiting feedback from each of the relevant journals, which will be disclosed once we are able to report on the progress of publication status.

These publications cover a combination of early and recent work and have been selected as the first group because they collectively begin to shape a foundation on which the more advanced work (especially clinical work) can refer. A table of these is included below.

The drafting of the next two manuscripts, in relation to our Phase 2 study of PHN and the Phase 1 oxymorphone patch study, has started. The drafts of these have also been useful in focusing business development discussions.

	Title (shortened)	Journal	Subject supported	Status
1	Topical Application of a Novel OxC Gel in a Rat Model of Peripheral Inflammatory Pain Produces Localised Pain Relief Without …	Journal of Pharmaceutical Sciences	**OXYCODONE**	**Published** Pub in July
2	TP Mixture (TPM®) as a novel lipid-based trans-dermal drug delivery carrier:	Drug Delivery and Translational Research	**TPM PLATFORM**	**Under review**
3	Randomized, DB, placebo-controlled study of TPM in metabolic syndrome & dyslipidemia	Not revealed	**ORAL EFFECTS OF TPM IN HUMANS**	**Submitted**
4	PK, safety & tolerability of a novel TPM®/ Oxycodone transderm patch system: Ph I study	Not revealed	**OXYCODONE**	**Submitted**
5	The effect of Tocopheryl Phosphates (TPM) on the Progression of Atherosclerosis in APOE-KO	Not revealed	**ORAL EFFECTS OF TPM IN RODENTS**	**Submitted**
6	Phase IIa oxycodone patch PHN study (no official title yet)	TBD	**OXYCODONE**	**In drafting**
7	Phase I oxymorphone patch pharmacokinetic study (no official title yet)	TBD	**OXYMORPHONE**	**In drafting**

ANIMAL HEALTH & NUTRITION
Dr Roksan Libinaki

Since our last update, the Animal Health & Nutrition business, has progressed with a strong focus on conducting studies to demonstrate product differentiation and validation of TPM® as a feed additive in livestock nutrition applications. While pigs have been the main focus for the R&D work undertaken to date, moving forward, a different species will now be used to further investigate the two major areas of opportunity for the business unit:

Project 1: Assessment of TPM®'s benefits in livestock growth and performance (assessments being carried out in pigs/poultry) and;

Project 2: Assessments of TPM®'s benefits in immune (milk quality) and fertility in dairy cattle.

Promising results were reported in early 2016, following the completion of a weaner pig study (young piglets). This study showed a statistically significant improvement in FCR or feed efficiency observed for the first 14 days of treatment (post-weaning), a highly stressful time in which growth performance is affected. Since then a second study, in which TPM® treatment was isolated to older (grower/finisher) pigs, has also been completed. The study indicated that, older pigs did not seem to benefit from treatment with TPM® (at doses 5 to 30 ppm) in the same way. The trial results in pigs, seen to date, suggest TPM® may provide its best effects in young piglets. Data provided from these pig studies, is providing an insight on TPM®'s use and application in this sector. Timing for inclusion, dose and defined benefits of TPM® will all assist in marketing packages designed to attract potential licences and partners and support regulatory activities, while informing the best study design for subsequent studies in other species.

The cattle study announced last month, is designed to assess the effect of TPM® supplemented feed on two commercially relevant end points; somatic cell counts (milk quality and immunity) and fertility (conception rates) in dairy cows. Since our last update, an additional farm site has been selected and initiated. The blinded, placebo controlled study, will run on-farm for at least 12 months. Each farm has 500+ cows on the study and it is likely to be completed by quarter 4, 2017.

Critically assessing potential advantages of TPM®, above and beyond established vitamin derived nutritive benefits, will be crucial to the success of Phosphagenics in this market. Evidence-based product differentiation, collected via these studies being undertaken, is a must. In a growing and 'noisey' feed additive market, such data will aid in validating, positioning and assessing the value of TPM® in this market.

Over the second half of 2016, we will also see the ramping up of our Business Development outreach program designed to keep potential licensees and partners in touch and involved with our R&D programs, trial results, etc. Feed is the largest input cost for producers, and therefore feed ingredient companies are constantly on the lookout for novel ingredients and feed additives to support better health and production outcomes and to encourage animals to reach their genetic potential.

BULK PRODUCTION & PERSONAL CARE
Greg Moses

As previously reported, ongoing plant improvements, production efficiencies and production planning continue to allow all orders to be completed on time or in most cases ahead of schedule. This facilitates a greater level of flexibility around scheduled maintenance and allows for improved safety assessments. Our focus continues to be expanding our partnerships and progress towards our ambitious performance goal of lower costs and improved margins.

An enhanced quality assurance project for our manufacturing process has been undertaken to support not only the rigour required for our ongoing manufacturing processes, but also the quality assessments of all our suppliers, further strengthening our end to end quality statement.

Our ongoing relationships and collaborations with customers such as Ashland, our Vital ET® global distributor, have been positive in driving the possibility of a product refresh and re-launch campaign in the first quarter of 2017. We believe this will drive renewed interest in the product to existing and, more importantly, new customers.

We also note that Le Métier de Beauté has recently launched two additional products that contain TPM® - Vital ET® Recovery Boost Face and Vital ET® Recovery Boost Body. This prestigious skincare brand now has more than 20 products in the market which contain TPM®.

These rejuvenated partnerships, combined with our ongoing collaborations with Themis (previously announced), are expected to lead to increased volumes of our TPM® and Vital ET® products. We continue to ready our current facility to support and take advantage of these opportunities as they arise.

CEO QUARTERLY UPDATE TELECONFERENCE

Interested parties are invite to participate in a teleconference.

Date: Wednesday, 3 August 2016

Time: 9:00am AEST

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

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