PHOSPHAGENICS

# Newsletter May 2013

**Dear Shareholders**

Welcome to our May newsletter. In the last quarter Phosphagenics announced several major initiatives reflecting an acceleration of our core research programs and the ongoing execution of our commercialisation strategy. The Company now has key partnerships in every division of our platform application.

The most significant commercial bulletin related to the announcement by our Indian partner, Themis Medicare, that, as well as distributing its own product in the Indian market, has sub-licensed our technology to Novartis India. Novartis is the global market leader of diclofenac products under its brand name Voltaren® and provides a significant global pharma endorsement of our TPM® technology.

Novartis AG is the third largest pharmaceutical company in the world with its Voltaren® branded products (tablets and gels) generating sales exceeding $750 million globally (ex US). The successful launch of TPM/diclofenac formulation in India will be the forerunner to potential expansion to other territories and for negotiating similar deals in other global regions.

In March the Company reported positive Phase 1 results of our oxymorphone patch. This study met all protocol endpoints, achieving delivery of the drug into the bloodstream for a continuous period of 72 hours. We also announced that our lead opioid candidate, TPM/oxycodone patch, had received ethics approval. The study of the optimised patch has now commenced en-route to accelerated Phase 2 and 3 trials.

We announced a more diversified opioid program which now includes a topical oxycodone product for localised pain indications such as neck pain and shingles related pain. This application is designed not to deliver opioids into the blood but to bind to receptors in or near the skin, eliminating the side effects normally associated with delivering opioids into plasma.

We are now in an excellent position to meet our commercial outcomes, with multiple optimised pain patch candidates. The addition of these new candidates has significantly enhanced the value of our pain franchise. Diversification of the pain franchise has also increased commercial opportunities going forward. Our Phase 1 oxycodone trial with the newly optimised patch developed by Labtec has commenced with results expected towards the end of July. Additionally, we aim to commence a multi-dose oxymorphone study in July, with results due by the end of the third quarter.

Adding oxymorphone and a topical oxycodone product to the pain portfolio will ultimately add significant shareholder value via multiple licensing opportunities. This diversification also maximises the probability of positive clinical outcomes for the portfolio.

In the second half of this year we will commence a Phase 2/3 study on oxycodone, an important milestone for the Company.

Adding an accelerated Phase 2 trial will not only increase the amount of data points available but enable the Company to do a smaller and cheaper Phase 3 than initially planned. Based

on significant global interest in our opioid program, a Phase 2 trial will demonstrate therapeutic efficacy of our patch systems much earlier and provide us with greater commercial flexibility should we decide to license one of our portfolio products at that stage.

Phosphagenics recently also announced that it is in advanced negotiations with Japanese pharmaceutical partner, Nippon Zoki, to develop a TPM/diclofenac product for the US prescription market. This market exceeds $300 million annually. The Company hopes to conclude any potential licensing opportunity in the second half of 2013.

In May we announced that we had signed a collaborative research agreement with the USDA (US Department of Agriculture). This research will be conducted in the US by the USDA's chief intramural scientific research agency, the Agricultural Research Service. Researchers will examine the effects and efficacy of the TPM® formulated products delivered via intra-mammary infusion using a protocol developed by the USDA.

Mastitis affects an estimated 15% of dairy cows at any time and in the US the cost to farmers in lost revenue and treatment is estimated at $2 billion per annum. The US represents less than 4% of the global market.

In April our rebranded personal care line, BioElixia®, launched in the United States both on-line and in retail stores. Additionally, the global company, General Nutrition Company (GNC), which operates over 8,000 stores, has launched a product manufactured by Phosphagenics that incorporates the TPM® technology. This product is part of GNC's Total Lean franchise and is designed to tighten and firm the skin's appearance.

It is clear that our team has been working diligently to aggressively progress our projects.

We thank our shareholders for their continued support and encouragement.

Dr Esra Ogru
Chief Executive Officer

# Key Project Update

## Opioid Pain Patch Program

The opioid patch program made significant progress during the last quarter. The oxymorphone patch completed Phase 1 clinical testing, demonstrating linear delivery of oxymorphone across the 3 day dosage period. The oxycodone patch received ethics approval to re-enter the clinic after further refinement by tesa Labtec in Germany. The tesa Labtec scientists visited Phosphagenics at the end of April to help manufacture the patch to be used in human studies. This Phase 1 trial is being conducted at the moment. Finally, results from our topical pain studies were discussed with key opinion leaders in the pain space, leading to the development of a clinical pathway using our oxycodone patch.

The clinical development of all three products will provide continuous news flow over the coming year.

Oxymorphone will re-enter the clinic in a Phase 1 multi-dose trial in the second half of the year. This will pave the way for Phase 2 studies in the appropriate pain model.

After successful completion of the current Phase 1 study, oxycodone will head into a multiple dose Phase 2 trial examining pain relief from the patch in the appropriate indication. This will be the beginning of the larger Phase 2/3 program and will provide the data necessary to power the pivotal Phase 3 study.

In addition to supporting the subsequent Phase 3 trial, the Phase 2 study will generate vital data much earlier than a larger Phase 3, hastening our ability to enter serious discussions and potential licensing opportunities with *Big Pharma*. It is entirely possible that the platform is licensed at the successful conclusion of Phase 2, leaving the licensee to conduct Phase 3 and product registration on their own terms.

The FDA landscape continues to evolve with respect to the way opioids are governed, and many of the recent changes are of immense benefit to the commercialisation of Phosphagenics' pain products. The recent ruling that prevents companies from manufacturing generic forms of the oxycodone tablet without including anti-abuse mechanisms is a case in point. As oxycontin was due to come off patent next year, this ruling is important in regard to maintaining higher margins and less competition for our patch.

| Program | H1/2013<br>Phase 1 | H2/2013<br>Phase 2 – Phase 3 |
|---|---|---|
| TPM/Oxycodone Patch | Phase 1<br>New patch system<br>Assessment underway | Efficacy trials – small<br>Efficacy trials – large group |
| TPM/Oxymorphone Patch | Phase 1 - completed | Efficacy trials |
| TPM/Oxycodone Topical | Preparing for Phase 2 | Efficacy trials |

# Mastitis

Phosphagenics recently announced an exciting research collaboration with the United States Department of Agriculture (USDA). Under the arrangements, it is expected that trials will commence in the second half of 2013. The studies will be conducted in the US by the USDA's chief intramural scientific research agency, the Agricultural Research Service, and the results are expected to be available for publication and global recognition upon completion. Phosphagenics will develop products containing active ingredients in combination with the Company's TPM® delivery technology to enable superior absorption and efficacy. The products will include the formulation previously successfully trialed by Phosphagenics in Australia, as well as a formulation containing Vitamin D. Researchers will examine the effects and efficacy of the TPM® formulated products delivered via intra-mammary infusion using a protocol developed by the USDA. It is intended to register these products.

Mastitis is a significant economic problem for dairy farmers globally, with losses arising from mastitis in lost production and treatment in the US alone amounting to $2 billion per annum. With the US representing less than 4% of the global herd there is clearly a major market opportunity for Phosphagenics. Currently antibiotics are the only viable treatment for mastitis. There is, however, a growing global concern in the overuse of antibiotics in animals as this leads to new bacterial strains and bacterial resistance.

Mastitis Management
AUSTRALIA

# Diclofenac update

Recently there have been two important developments regarding Phosphagenics' non-steroidal anti-inflammatory diclofenac product.

In our previous newsletter we indicated that our commercial partner, Themis Medicare, was planning to launch the Phosphagenics-formulated diclofenac product in the Indian market. In April Themis announced that it had agreed, with our consent, to sub-license our intellectual property to Novartis India, a subsidiary of Swiss pharmaceutical giant, Novartis AG, the third largest pharmaceutical company in the world. Under the term of its arrangements, Themis would manufacture and sell the TPM/diclofenac to Novartis India. Phosphagenics will receive royalties on such sales.

Global sales (excluding the US) of Novartis' diclofenac products, marketed under the brand name Voltaren® (or Vovaren in India), exceed US$750 million gels and tablets. Novartis is the clear global leader for diclofenac products.

With the formula established by Phosphagenics and with few regulatory hurdles in many other countries where it is sold as an OTC product, Phosphagenics plans to expand its TPM/diclofenac formulation into new regional markets.

We are the worlds only producer of TPM® and this technology is protected by a robust intellectual property portfolio. This security mitigates the risk of copycat competitor products.

In addition to the new Indian arrangements, Phosphagenics also reached agreement with Japanese company, Nippon Zoki, to develop an anti-inflammatory diclofenac formulation for the US prescription market. This product to treat acute pain will have to proceed through standard FDA clinical trial processes and, because several diclofenac products have already been approved in the US, we expect a rapid and straightforward path to market.

THEMIS MEDICARE

NOVARTIS

# Injectable Antibiotics: Mylan

In November 2012 Phosphagenics announced that it had entered into a licensing arrangement with Agila Specialties Private Limited (recently purchased by Mylan) to develop an injectable antibiotic product that incorporates TPM®. Under the terms of the arrangements, the company was paid an upfront payment and will be paid a royalty on future sales.

The TPM® version, which has superior characteristics to the current product, should provide a significant clinical and commercial advantage for the product. The patent covering the currently marketed antibiotic product will expire in 2014, leaving open the path for the entry of generic products. The first company to launch the generic version of product normally obtains a marketing advantage over its competitors.

In February US based Mylan Inc. announced that it had reached an agreement with Strides Arcolab to purchase its subsidiary, Agila Specialties Private Limited, for $1.6 billion cash.

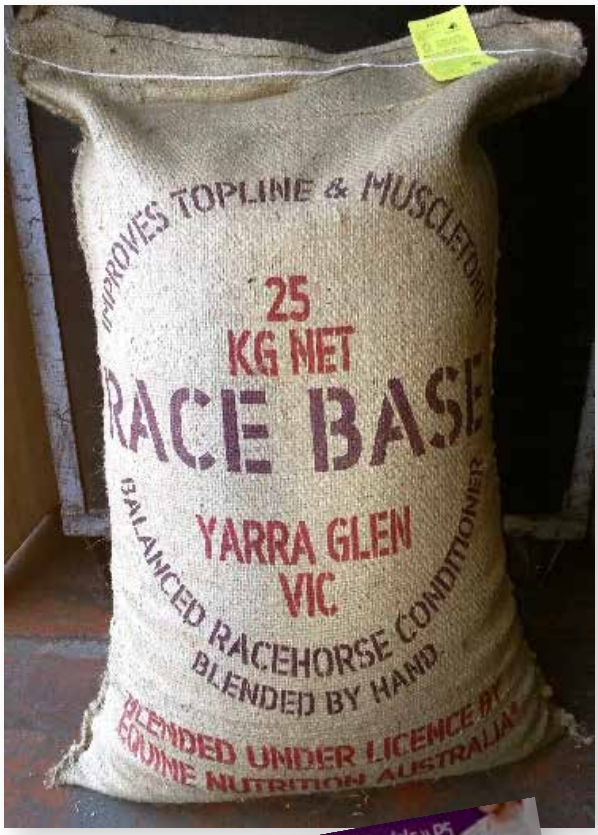
Mylan is one of the world's leading generic and specialty pharmaceutical companies, marketing 1,100 different products to customers in over 150 countries. It employs a workforce of over 18,000 people and has annual revenues of $6.1 billion.

Following the acquisition of Agila, Mylan will account for approximately 70% of the regulated injectable market. Phosphagenics is collaborating with Agila Specialties on other products.

agila

# Animal Health ... ENA/EEA

Our versatile TPM® delivery platform has extensive application in animal health. In mid-2012 Equine Nutrition Australia released a range of breeding feeds incorporating TPM® which were specifically aimed at the lucrative thoroughbred breeding market. While thoroughbred studs are known to be conservative in their approach to their expensive bloodstock, take-up was swift by early adopters of the TPM® technology. To date Equine Nutrition Australia (ENA) has 37 studs in Australia either using or trialling the feeds on select weanling or yearlings. Following that success, ENA launched four more feeds, including full work feeds for racehorses.




One of the most prominent clients of our partner's feeds is BC3 Thoroughbreds, who recently purchased Black Caviar's half-brother for $5 million, making it the most expensive thoroughbred yearling in Australasian history. This horse, along with all of BC3's yearlings, is using ENA's TPM® Race Base® in preparation for its racing career. ENA has achieved a great deal in a short time demonstrating the ongoing validation of the scope and versatility of TPM®.


Equine Nutrition
AUSTRALIA

## Equine Ergogenics Australia (EEA)

In late 2012 Phosphagenics teamed up with ENA to create a jointly owned company called Equine Ergogenics Australia. EEA formulates and manufactures high technology based racehorse supplements. EEA has three supplements in commercial production and distribution known as Obla Max®, Obla Plus® and Phytate X Max®. Another three supplements will be launched later this year. All products incorporate TPM®.

Since its inception, EEA has appointed an Asian distributor, Equine Ergogenic Asia, and gained approval for the use of the supplements for racehorses by the prestigious Singapore Turf Club. Significantly, one of Singapore's leading trainers began trialling Phytate X Max® and was so convinced by its benefits that all of his horses are now fed these unique products. There are now several well established trainers in Singapore using our products.

Recently EEA has begun marketing Phytate X Max® in Australia and has many high end stables using the products.

EEA is currently involved in negotiations with companies in several global territories, including the UAE, Great Britain and Europe.



Equine Ergogenics
AUSTRALIA

Phytate X MAX

DAILY TPM® AND PRO-VITAMIN A SUPPLEMENT TO LIMIT PHYTATES ASSOCIATED WITH LUCERNE AND GRAIN. PHYTATES BLOCK THE UPTAKE OF IRON

For Racing Professional Use Only. A Equine Ergogenics Australia® Performance Product Built On Science

# BioELIXIA®


The BioElixia® brand and products continue to gain market exposure with interest being shown in the unique and cutting edge TPM® delivery technology in the skin and body care segment. In a very competitive market BioElixia® is differentiated by the outstanding scientific based products that deliver results.

This TPM® delivery technology is the basis of a new product range which will be launch in Australia in Q3, 2013. These products will target stretch marks and the Company is planning an aggressive Australian marketing campaign around this new BioElixia® line, involving TVSN and major retailers.

The BioElixia Cellulite Contour Crème® has been successfully launched in the United States via a dedicated e-commerce website as well as in several retail chains.

The multi-billion dollar US nutritional company, GNC, will launch a firming and toning cream under its own brand manufactured by Phosphagenics incorporating the TPM® delivery technology. The product forms part of GNC's Total Lean franchise and is designed to tighten and firm the skin's appearance. It was launched in May. GNC currently has 8,200 stored in 55 different countries. There are 6,200 stores in the USA. They are one of the world's largest retail chains specialising in health and well being.



GNC
LIVE WELL.

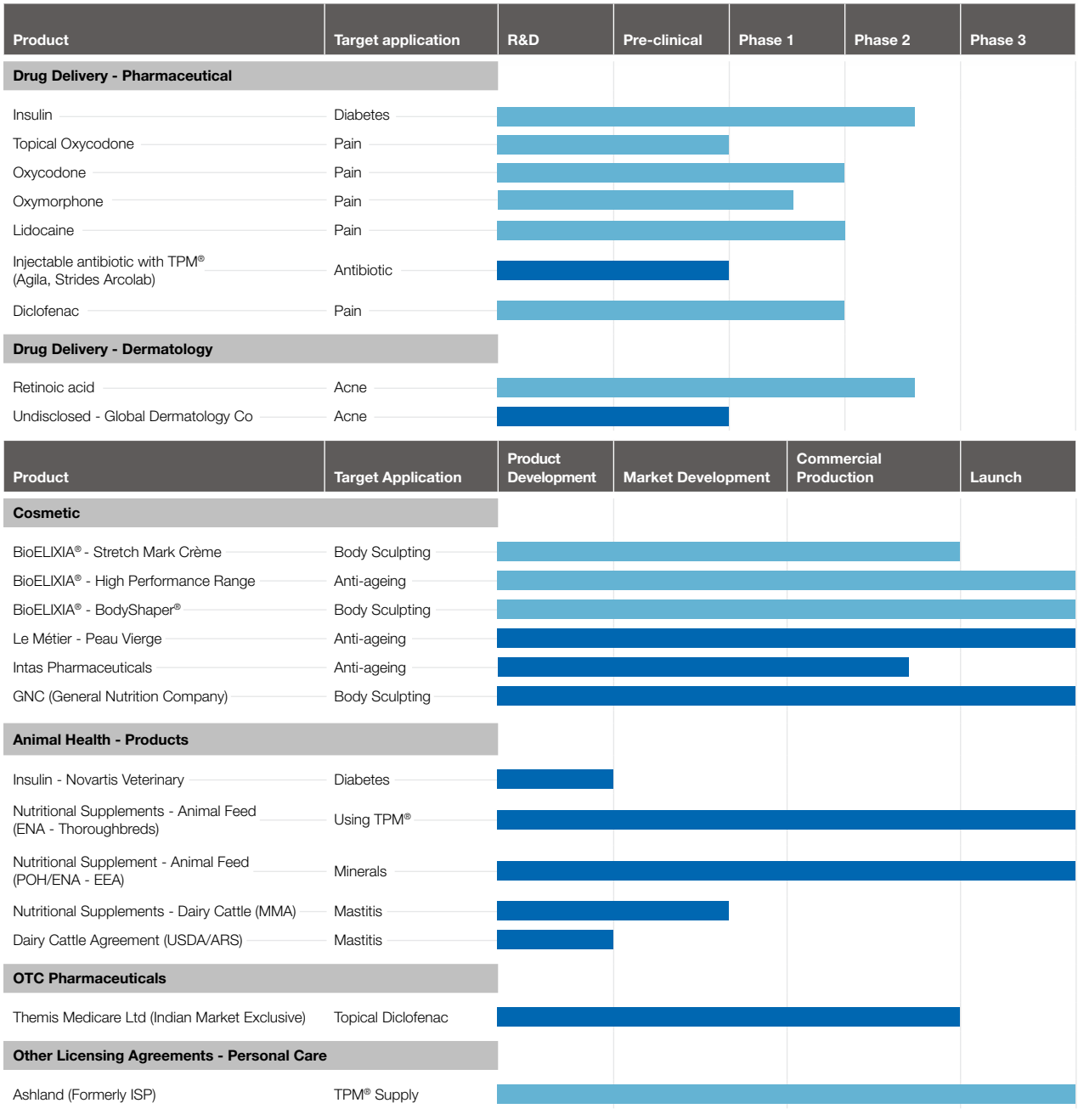
# Financial Position

The changes to the R&D Tax Incentive announced in the budget will have no impact on Phosphagenics ability to claim the incentive from the federal government. This is an important source of funding for companies such as ourselves who have a fully integrated R&D capacity with a very busy clinical program planned. This means that the costs of our trials are reduced to the extent that we can claim the incentive which amounts to 45% of those costs.

Our financial position remains solid with $17 million approximately in cash at the beginning of the year. To this we can add approximately $6.8 million for the R&D Tax incentive earned so far (receivable in two tranches, one this quarter and the other in the final quarter). Even though we plan to be in the clinic continuously with various products during 2013, we will still be in a comfortable cash position at calendar year end 2013.

New revenue streams from Themis and GNC will start to make a contribution to earnings in the second half.

# Product Development Update

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