



PHOSPHAGENICS

**Newsletter** February 2013

### **Dear Shareholders**

We begin 2013 with great expectations as we prepare for a number of important clinical trials during the year, the first of which will commence in early February on our latest addition to our pain portfolio, oxymorphone.

Commercially, we expect to expand our earnings pool to include seven separate revenue streams by the end of June 2013. Our partners, Intas Pharmaceuticals Ltd, Themis Medicare Ltd and GNC, are all launching TPM<sup>®</sup> inspired products in the first half to add to our existing sources of revenue from Le Métier de Beauté, Elixia<sup>®</sup>, Equine Nutrition Australia (ENA) and Ashland Inc. (formerly ISP).

With the initiation and continuation of clinical development, either by itself or with partners in several areas, such as dermatological products, animal health products, Injectables (such as antibiotics) and Rx diclofenac products for the USA market, the Company is hopeful that trial data will lead to commercialisation opportunities.

This year should also see the rollout of new cosmetic products.

The past year demonstrated that our platform technology has application in many and varied fields, some of which cannot always be anticipated. The deal with Agila in India to use TPM<sup>®</sup> in an injectable antibiotic product is a good example of this.

While it is important to develop a solid earnings base, in 2013 Phosphagenics' management and most investors' attention will remain focused on our opioid patch clinical program which was recently expanded to include oxymorphone, the third largest selling opioid in revenue. Oxycodone, the largest selling opioid, remains the primary focus and the Company is exploring options for its use beyond systemic exposure. The development of oxycodone and oxymorphone are unique as no other pharmaceutical company has commercialised either drug for delivery via a patch. The success of the program itself will also be unique as no company has commercialised more than one transdermal opioid.

The potential to build a pain portfolio with several opioids for transdermal delivery, if successful, will add considerable value for shareholders. The oxymorphone and oxycodone clinical trial program will be underway during the early part of 2013. The successful implementation of our platform technology will make Phosphagenics a significant biotechnology company globally.

We have had a number of institutions and brokers interested in our activities and this has initiated coverage of our Company by brokers, including Macquarie Securities, Nomura Equity, Octa Phillip Financial Group and Lux Research Inc. Some of these reports can be found on our website.





## December 2012 Quarter

In the final quarter of 2012 we announced a number of important initiatives. In October we entered into a license agreement with Agila for the use of TPM® in an injectable antibiotic product. While this was the first time that TPM® was used in an injectable, it is likely to lead to similar deals in the future.

Additionally, we announced the launch of three new racehorse supplements in Asia, after receiving approval of these products by the Singapore Turf Club. This followed on from a study we conducted in racehorses earlier in 2012. At that time we formed a joint venture with our partner, Equine Nutrition Australia, to market the products through an Asian distributor. Other regions will be targeted in 2013. The significance of this is that the potential use of TPM® in animals represents by far the largest potential for the sale of TPM® as an ingredient.

The third commercial agreement announced in the last quarter was the arrangement with US nutritional company, GNC, for the Company to supply a firming cream formulation throughout their extensive retail network. The product will be launched in the USA during the second quarter of 2013.

Lastly, in December 2012 we announced an expansion of our pain franchise to include the powerful opioid, oxymorphone, in our clinical program. The experience gained by the Company in patch development and opioid formulation over the years, coupled with the TPM® technology, potentially places us in a unique position of becoming a global leader in pain management.



We thank you for your continuing support.

Dr Esra Ogru  
Chief Executive Officer



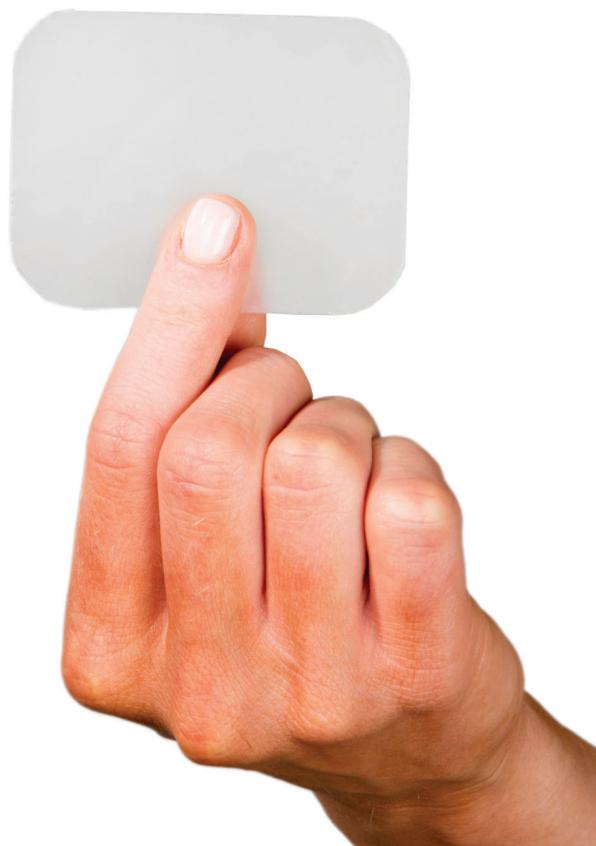
## Opioid Patch Program: Expansion of Pain Portfolio

The global market for opioids used in the treatment of pain is estimated to exceed \$14 billion annually. Phosphagenics intends to become a global player in the pain market over the next decade by leveraging its technology and the experience gained during the development of the oxycodone patch to other opioids. The first product to be added to its pain portfolio is oxymorphone. In the event of a successful development of its initial opioid candidates, other transdermal opioid products will follow.

Most clinicians consider opioids to be the first-line therapy for the treatment of both acute and chronic pain. Long-term opioid therapy for chronic pain is accepted by pain specialists as appropriate for patients who suffer from debilitating diseases such as cancer so long as they are treated in line with best medical practices.

There are more than a dozen opioids used commercially for the treatment of pain. While morphine is still considered to be the golden standard in pain management, stronger and diverse opioids have been developed to cater for individual variability as well as the need for opioid rotation.

The rationale for opioid rotation is predicated on the basis that responses to different opioids vary markedly in an individual. In part, this may be due to genetic variation in the pattern of opioid receptors. Additionally, it is not uncommon that after an opioid has been administered for a long period, tolerance develops in a receptor-specific manner, and rotation to another opioid is used by clinicians to produce different results to those achieved by the previously administered opioid drug. Opioid rotation has further clinical utility as it may also reduce or eliminate adverse side effects.





There are only two opioids currently administered transdermally. These are the very powerful opioids, fentanyl and buprenorphine.

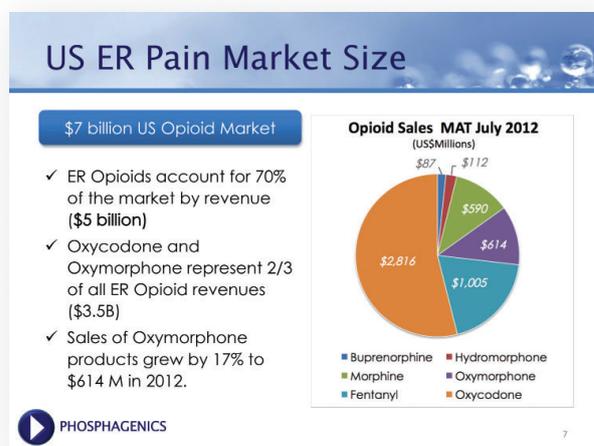
At its peak, the market for the fentanyl patch exceeded \$2 billion in sales annually. Before the development of this opioid as a patch, sales of the oral form were approximately \$50 million. Since becoming generic, fentanyl sales have dropped drastically, but still exceed \$1 billion.

Buprenorphine is approximately 40 times more powerful than morphine while fentanyl is around 100 times more powerful. Consequently only small quantities of these drugs are needed to provide therapeutic effect making them excellent candidates for transdermal administration. Oxycodone is two times more powerful than morphine while oxymorphone is seven times more powerful. Because of the poor oral bioavailability of oxymorphone relative to oxycodone, a much smaller amount of oxymorphone relative to oxycodone is required to provide a therapeutic dose.

In six years since the FDA approved an oxymorphone extended release formulation, the market for this opioid has grown from negligible levels to exceed \$600 million in sales during 2012, an increase of over 17% from the previous year. Oxymorphone is now the third largest opioid in terms of sales and, together with oxycodone, accounts for about 70% of the \$5 billion extended release US market.

Oral extended release formulations dominate the opioid markets. Oxymorphone extended release has over 10 years of patent protection, whereas oxycodone extended release version will come off patent this year with the resultant sales of generic oxycodone formulations hitting the market.

These factors all point to making oxymorphone an ideal companion product for the oxycodone patch which is due to return to the clinic shortly.



## Themis to launch TPM<sup>®</sup> diclofenac pain product in March

Phosphagenics's Indian partner, Themis Medicare Limited, will launch its TPM<sup>®</sup> formulated topical non-steroidal anti-inflammatory drug (NSAID) gel in March.

The product, to be called "Instanac TPM Gel" combines the NSAID diclofenac with Phosphagenics' proprietary TPM<sup>®</sup> platform delivery technology to enable superior absorption and deeper penetration of the drug which is used to reduce inflammation and pain.

Under the terms of the licensing agreement signed in late 2011, Themis agreed to pay POH an undisclosed upfront fee and royalties on sales. In addition, Themis was granted the right to manufacture products on behalf of other companies for distribution in the Indian market.

The global diclofenac market exceeds US\$1 billion per annum and is administered as a tablet as well as topically.

The Indian product launch will result in immediate revenues for Phosphagenics as well as a likelihood of licensing arrangements with additional companies for the product in other global regions.

The product launch is further evidence of the versatility of the company's proprietary TPM<sup>®</sup> platform delivery technology. Our technology has enabled Themis to commercialise a product that is absorbed more rapidly and effectively than other marketed products. We hope that the superior product will be adopted as the product of choice for pain and inflammation in the Indian market, and subsequently in other global regions."

Themis manufactures, formulates and markets its own products throughout India and internationally. It has four state of the art API manufacturing facilities and 2 formulation manufacturing sites in India. It supplies products to more than 42 countries world wide.



## ELIXIA®

### **New General Manager Appointed**

After a thorough review of Elixia's business operations, Phosphagenics appointed Greg Moses as General Manager of the Personal Care division in November 2012.



Greg's experience spans wholesale and retail brand development. His previous roles have included General Manager at Australian Natural Brands and Purity Australia, working with popular brands In Essence and Oil Garden Aromatherapy. He has also worked with leading Australian brand, Natio Pty Ltd. Greg is renowned for his ability to build brands with an outcome of strong sales growth.

He also spent several years as a Business Manager for Myer Grace Bros and was part of the team responsible for turning the failing Bendigo store into a profitable operation.

Greg's strong retail, product development and promotions experience, along with his people skills and great enthusiasm for the brand, augurs well for returning Elixia® to a satisfactory level of revenue and profit. He is confident that 2013 will see Elixia® achieve revenues at a level more consistent with those achieved after its launch in 2011.

"The key to making Elixia® a successful brand is having the right offer at the right time and place, with the right value and service. Consistency of brand communication is paramount in lifting the brand to new levels," says Greg.

### **BioElixia® - US E-commerce and Retail Launch**

Phosphagenics has launched its hero product, BioElixia® BodyShaper™ Cellulite Contour Crème, through a number of strategic retail partners in the USA. This has been timed to maximise sales during the upcoming northern spring/summer season. At this stage, retail partners for BioElixia® BodyShaper™ include Henri Bendel, Fred Segal, [www.amazon.com](http://www.amazon.com), [www.dermstore.com](http://www.dermstore.com) and [www.skincarerx.com](http://www.skincarerx.com) – and this list is expected to grow. Phosphagenics is also currently developing its own e-commerce website – [www.bioelixia.com/us/](http://www.bioelixia.com/us/) – for BioElixia® BodyShaper™ sales directly to US consumers to be launched in February 2013.

To support these launch activities, the company has engaged a public relations consultant for both traditional and online publicity, with articles already appearing in Star Magazine (circulation approx. 750,000) and New You magazine (circulation approx. 250,000).





## Personal Care: GNC Agreement

In December 2012 Phosphagenics announced an agreement with US health and nutrition giant, GNC, to supply a firming/toning cream final product. GNC, which has 7,900 retail locations (6,000 of these in the USA), will brand and market this product throughout its expansive network.

In addition to its extensive retail presence, GNC's e-commerce business is substantial with 5.8 million active customers, as well as 3.1 million unique visits per month to its website.

GNC will market the product within its lucrative diet products category. GNC's extensive global reach and significant marketing network should lead to a successful launch of the product.

In other areas within personal care, Le Métier de Beauté and Ashland Inc. (formerly ISP) will be solid revenue contributors for 2012-2013, with the amount of TPM® being used to meet the increasing demand from personal care continuing to grow strongly (up over 20% in 2012).





## Animal Health Update

In October 2012 Phosphagenics announced that the Singapore Turf Club had approved our supplements product for sale to horse trainers in Singapore. In partnership with Equine Nutrition Australia (ENA) we have now developed five different products for the Asian market using our patented TPM® technology.

Through trials conducted in Victoria over the last two years, these products have been specifically developed to meet the extra physical demands of thoroughbred racehorses. They are formulated with ingredients known to improve the animals' health and wellbeing and provide the extra nutrients needed to meet the rigors of training and racing.

Phosphagenics and ENA have also formed a jointly owned marketing company, Equine Ergogenics Australia (EEA), to enable the sale of these products globally, and have since appointed a distributor to market the products in ten leading racing countries in Asia.



**Equine Nutrition**  
AUSTRALIA



**Equine Ergogenics**  
AUSTRALIA

“Sales are gaining traction with considerable interest generated by the sale of an ENA TPM®-fed yearling being purchased by Gai Waterhouse at the recent Magic Millions yearling sales on the Gold Coast,” says EEA’s CEO, Rob Neely.

“EEA products are also finding favour with several top trainers in Australia and Asia,” he adds. “We plan to launch three more products this year as well as some more TPM® enhanced feeds.

“EEA is hopeful that in coming months we will receive approval from other Asian racing authorities to sell our products. We are also looking to appoint distributors in other global territories.”



**Mastitis Management**  
AUSTRALIA

### **Mastitis Management Australia Ltd (MMA)**

Mastitis remains a major focus in the animal health area and preliminary work in relation to upcoming trials is continuing. We expect to update the market on these trials shortly.

MMA is also working with one of Australia’s largest animal feed companies for the inclusion of our Mastitis formula for use as a prophylactic in dairy feeds.



## R&D: Tax Incentive

In 2011 the Federal Government introduced a tax rebate incentive scheme for technology companies. The tax incentive gives a 45% rebate for the tax year period (i.e. from 1 July 2011 - 30 June 2012).

We estimate that for the 2011-2012 financial year Phosphagenics should receive approximately a \$3 million payment. This should be received in the current half year. The payment for the 2012-2013 period should be around \$3.5-\$4 million and is likely to be received towards the end of this calendar year.

With a growing revenue stream likely from personal care and animal supplements, additional to the tax incentives, cash inflow should show a strong increase over the next two years. This is without reliance on any upfront payments that may be negotiated in pharmaceuticals or other areas.



# Product Development Update

Product	Target application	R&D	Pre-clinical	Phase 1	Phase 2	Phase 3
<b>Drug Delivery - Pharmaceutical</b>						
Insulin	Diabetes	[Phosphagenics Project]				
Oxycodone	Pain	[Phosphagenics Project]				
Oxymorphone	Pain	[Phosphagenics Project]				
Lidocaine	Pain	[Phosphagenics Project]				
Injectable antibiotic with TPM (Agila, Strides Arcolab)	Antibiotic	[Collaborative Project for commercial partner]				
Diclofenac	Pain	[Phosphagenics Project]				
<b>Drug Delivery - Dermatology</b>						
Retinoic acid	Acne	[Phosphagenics Project]				
Undisclosed - Global Dermatology Co	Acne	[Collaborative Project for commercial partner]				
Product	Target Application	Product Development	Market Development	Commercial Production	Launch	
<b>Cosmetic</b>						
ELIXIA®	Natural Anti-ageing	[Phosphagenics Project]				
ELIXIA® - High Performance Range	Anti-ageing	[Phosphagenics Project]				
ELIXIA® - BodyShaper®	Body Sculpting	[Phosphagenics Project]				
Le Métier - Peau Vierge	Anti-ageing	[Phosphagenics Project]				
Intas Pharmaceuticals	Anti-ageing	[Collaborative Project for commercial partner]				
GNC (General Nutrition Company)	Body Sculpting Cream	[Collaborative Project for commercial partner]				
<b>Animal Health - Products</b>						
Insulin - Novartis Veterinary	Diabetes	[Collaborative Project for commercial partner]				
Nutritional Supplements - Animal Feed (ENA - Thoroughbreds)	Antioxidants, Minerals	[Collaborative Project for commercial partner]				
Nutritional Supplement - Animal Feed (POH/ENA - EEA)	Minerals	[Phosphagenics Project]				
Nutritional Supplements - Dairy Cattle (MMA)	Mastitis	[Collaborative Project for commercial partner]				
<b>OTC Pharmaceuticals</b>						
Themis Medicare Ltd (Indian Market Exclusive)	Topical Diclofenac	[Phosphagenics Project]				
<b>Other Licensing Agreements - Personal Care</b>						
Ashland (Formerly ISP)	TPM® Supply	[Phosphagenics Project]				

 Phosphagenics Project  
 Collaborative Project for commercial partner

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