

# PHOSPHAGENICS LTD (POH)

## Leveraging TPM<sup>®</sup> Technology across Multiple Products and Markets

### SPECULATIVE

4 May 2011

#### Share Trading Info

ASX Code	POH
Current Share Price (cps)	14.5
Trading Low/High (Rolling Year)	8.5c - 18.5c
Mkt Capitalisation (undiluted) \$m	119.4
Current Cash (Est)	\$8.5m

#### Issued Capital (m)

Total Ordinary Shares	823.6
Unlisted Options	15.0
Total Diluted Securities	838.5

#### Board of Directors\*

Jonathan Addison	Non Executive Chairman
Harry Rosen	President and Joint CEO
Dr Esra Orgu	Joint CEO
Don Clarke	Non Executive Director
Stuart James	Non Executive Director
Dr Sandra Webb	Non Executive Director

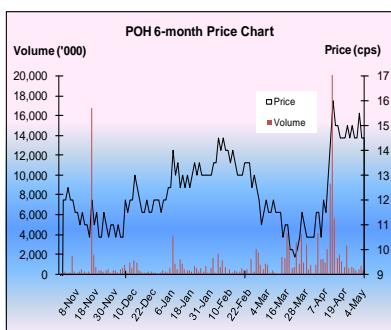
\* Further details on Page 16

#### Major Shareholders

Orbis Global Equity Fund Ltd	14.6%
Mr Harry Rosen	7.8%
Mr Simon M West	6.1%

#### Important Disclosure

Investors should be aware that Phosphagenics Ltd is a corporate client of Alpha and that Alpha will receive a consultancy fee from Phosphagenics Ltd for compiling this research report.



### SUMMARY

Targeted Penetration Matrix (TPM<sup>®</sup>) is Phosphagenics' in-house proprietary delivery technology and is the foundation for the company's development of pharmaceutical products, cosmetics & personal care products as well dermatological products.

The attractiveness of TPM<sup>®</sup> technology to companies involved in dermatology drug development, skincare and cosmetics is underpinned by the ability of TPM<sup>®</sup> technology to deliver many compounds topically in a non-invasive manner without causing sensitisation or irritation. Accordingly, the cosmetic industry is a highly attractive market for POH given the low cost of entry and the speed with which products can be commercialised.

#### TPM<sup>®</sup> Pain Patch

The company's core development product is the world's first oxycodone pain relief patch. POH has recently completed a placement in order to commence Phase II clinical trials for its oxycodone pain relief patch planned later this year.

The product will become the first to provide chronic pain sufferers with a patch that will provide sustained-release oxycodone into the bloodstream.

The company has conducted two successful Phase I studies in 2009 on its TPM<sup>®</sup>/oxycodone formulation. A third study was also conducted to identify the optimal dose of oxycodone required in a patch to deliver pain relief, using the TPM<sup>®</sup>/oxycodone patch delivery system. The study demonstrated that the extended dosing period of 14 days enabled steady state delivery of Oxycodone into the bloodstream when applied daily.

#### Commercial Scale Manufacture in progress

POH is currently working on the commercial development of the TPM<sup>®</sup>/oxycodone pain patch and has entered into an agreement with 3M for a commercial-scale patch manufacturing process.

The commercial scale manufacture is expected to be completed in the 3<sup>rd</sup> quarter of 2011, at which point Phase II/III clinical trials will commence.

#### Attractive Market Opportunity

The US is the company's major target market for its TPM<sup>®</sup>/oxycodone patch, with an estimated 75 million Americans experiencing acute pain each year. The demand for pain drugs continues to increase, with the market expected to be worth

US\$50 billion annually by 2020. There is a demand for pain treatments that:

- i. Have fewer side effects for patients currently using opioids
- ii. Will improve pain management (meaning shorter hospitalisation) and
- iii. Are a less abusable form of oxycodone. POH has been working closely with its pain advisory board to implement a risk minimisation plan on order to demonstrate the anti-abuse properties of the TPM<sup>®</sup>/oxycodone patch.

Further, TPM<sup>®</sup>/oxycodone patches have an opportunity to gain market penetration as the regulatory environment for opioids in the US is highly stringent.

POH is also expected to submit an IND application to the FDA in the 4<sup>th</sup> quarter of 2011. Once regulatory approvals in the US are granted, the company plans to enter the Australian, SE Asian and European Union markets.

**Timeline for Development of TPM<sup>®</sup>/Oxycodone Patch**

	2011		2012			
	Q3	Q4	Q1	Q2	Q3	Q4
Completion of 3M patch system	█					
Commence Phase II/III Trials in Australia	█					
Submit IND dossier to the US FDA		█				
Continuation and completion of Phase III Trials			█			
Completion of relevant toxicological studies			█			

**AOP9604 – BodyShaper Cellulite Contour Crème™ (Formerly AOD9604)**

POH is developing AOP9604 as a topical anti-cellulite cream using TPM<sup>®</sup> technology after clinical trials conducted by Metabolic Pharmaceuticals for AOP9604 as an anti-obesity drug failed and POH believe that, in part, the reason for this was the method of delivery, rather than its efficacy. In those trials, the drug was delivered orally and as the fat cells which are to be targeted in this cosmetic are topical (under the skin) POH believe that the delivery of the AOD peptide via the skin using TPM<sup>®</sup> technology is a superior method, as it avoids the stomach, digestive system and blood stream.

An independent study currently underway in the US on a cosmeceutical product (launched in April 2011 by POH as *BodyShaper Cellulite Contour Crème™*) has shown that after 28 days of application, the visible appearance of cellulite was significantly reduced by as much as 40% at the areas of application.

A substantial market has emerged in the US for anti-cellulite products. AOP9604 has the ability to gain a foothold in this market as it is a product with strong proof of efficacy and would

require a low cost of entry, as POH had already sourced the peptide from a low-cost manufacturer in Taiwan.

### Adequate Funding – Moving towards a self-funding model

Available cash as at 31 March 2011 was \$8.5 million, boosted by a recent \$7.55 million placement of 83.9 million shares at 9 cents per share to institutional and professional investors. The monthly cash burn rate expected is to be \$0.5 million over the course of 2011. The balance sheet is debt free.

Proceeds from the placement are also expected to be used to fund rollouts of its new cosmetic range, including an anti-cellulite cream.

POH is progressing towards a self-funding model. Based on cash flow projections, POH expect to be cash flow positive in 18 months as a result of Elixia<sup>®</sup> personal care product sales<sup>1</sup>. Elixia<sup>®</sup> is already sold in Australia, and other cosmetics containing TPM<sup>®</sup> are sold via US partners (e.g. Métier Tribeca LLC). An anticipated product launch and expansion throughout SE Asia is planned for later this year. As of May 2011, Elixia<sup>®</sup> will be available through a variety of different distribution channels Australia-wide, including online e-commerce sales, large retailers with stores, as well as via other online outlets and strong home-shopping partnerships.

At present, cash generated from the 'faster to market' personal care products will assist in funding higher-value pharmaceutical opportunities to the point where a rewarding partnership/license agreement can be negotiated.

### Capital Structure

The company's top 20 shareholders account for nearly 54% of the total shares on issue and are a mix of institutional investors, management & founders and retail investors.

In addition to its shares being listed on the ASX, POH's ADR's (PPGNY) are traded on the OTCQX in the US.

Shares/Options on Issue	Million	Expiry Date
Total Ordinary Shares	823.6	
Unlisted Options		
- Exercise Price 24c	1.60	22-May-11
- Exercise Price 36c	0.10	28-Aug-11
- Exercise Price 26c	1.30	06-Jun-12
- Exercise Price 14c	5.00	31-Mar-13
- Exercise Price 15c	1.90	17-Aug-13
- Exercise Price 15c	2.40	17-Jun-14
- Exercise Price 13c	2.65	30-Jun-18
<b>Total Unlisted Options</b>	<b>14.95</b>	
<b>Total Issued Securities</b>	<b>838.5</b>	

<sup>1</sup> Elixia<sup>®</sup> personal care products were launched in April 2010. There were six products in the initial range, all developed from a topical pharmaceutical delivery platform based on scientific and clinical research. A new range of Elixia<sup>®</sup> products were launched into the Australian market in April 2011.

# 1. COMPANY OVERVIEW

## 1.1 Operations

The operations of Phosphagenics Ltd (ASX Code: POH) involve utilising its unique TPM<sup>®</sup> technology for the production, sale and licensing of products in two areas: nutraceutical products and pharmaceutical products. The nutraceutical business develops active ingredients for the market segments, such as dietary supplements (vitamin capsules and tablets) and functional foods and beverages (nutritionally enhanced foods) and personal care products.

The pharmaceutical division is focused on drug delivery, which involves enhancing delivery of existing drugs orally or through the skin.

## 1.2 Strategy

The company’s development and commercialisation activities are focused on developing differentiated products that possess significant global market size potential, a clear competitive advantage in their market segment (such as high convenience or being able to satisfy on unmet need) and an ability to be used in multiple applications (such as products with relevance in multiple market segments).

The route to market for POH’s products is through partnering at the appropriate stage in a product’s development, so as to maximise return on the Company’s R&D investment. The company will however aim to manufacture and supply the active ingredients to its partners or distributors where commercially feasible.

## 1.3 Research & Development and Product Pipeline



## **2. OVERVIEW OF TPM<sup>®</sup> TECHNOLOGY**

TPM<sup>®</sup> was developed in-house at the Phosphagenics laboratory and is a result of nearly 10 years of research and development. The technology was developed from a mixture of two tocopheryl phosphates and is designed to enhance and improve the absorption of pharmaceuticals, cosmetic and dermatological actives. TPM<sup>®</sup> derived from natural Vitamin E and is GRAS<sup>2</sup> approved for human oral delivery.

The advantages and benefits of the TPM<sup>®</sup> delivery technology:

- First in class delivery technology
- TPM<sup>®</sup> technology has undergone a number of toxicology studies and has achieved proof of concept in delivering drugs both topically as well as transdermally.
- TPM<sup>®</sup> does not alter the active compound, but instead alters the lipidic structure of the stratum corneum to enhance absorption of small molecules or peptides into the skin, locally or systemically.
- Superior versatility to other delivery systems as it can be formulated into a gel, patch, spray, micro-emulsion or nanoparticle entrapment system<sup>3</sup>. TPM<sup>®</sup> can be formulated and adapted to deliver many therapeutic small molecules or peptides for dermal delivery.
- Non-invasive and non-irritant
- Acts to enhance the oral absorption and bioavailability of compounds in the body.
- The TPM<sup>®</sup> delivery technology is well suited to products in a growing market as products can be brought to market relatively quickly and at relatively low expenditure.

### **2.1 Patents and Intellectual Property**

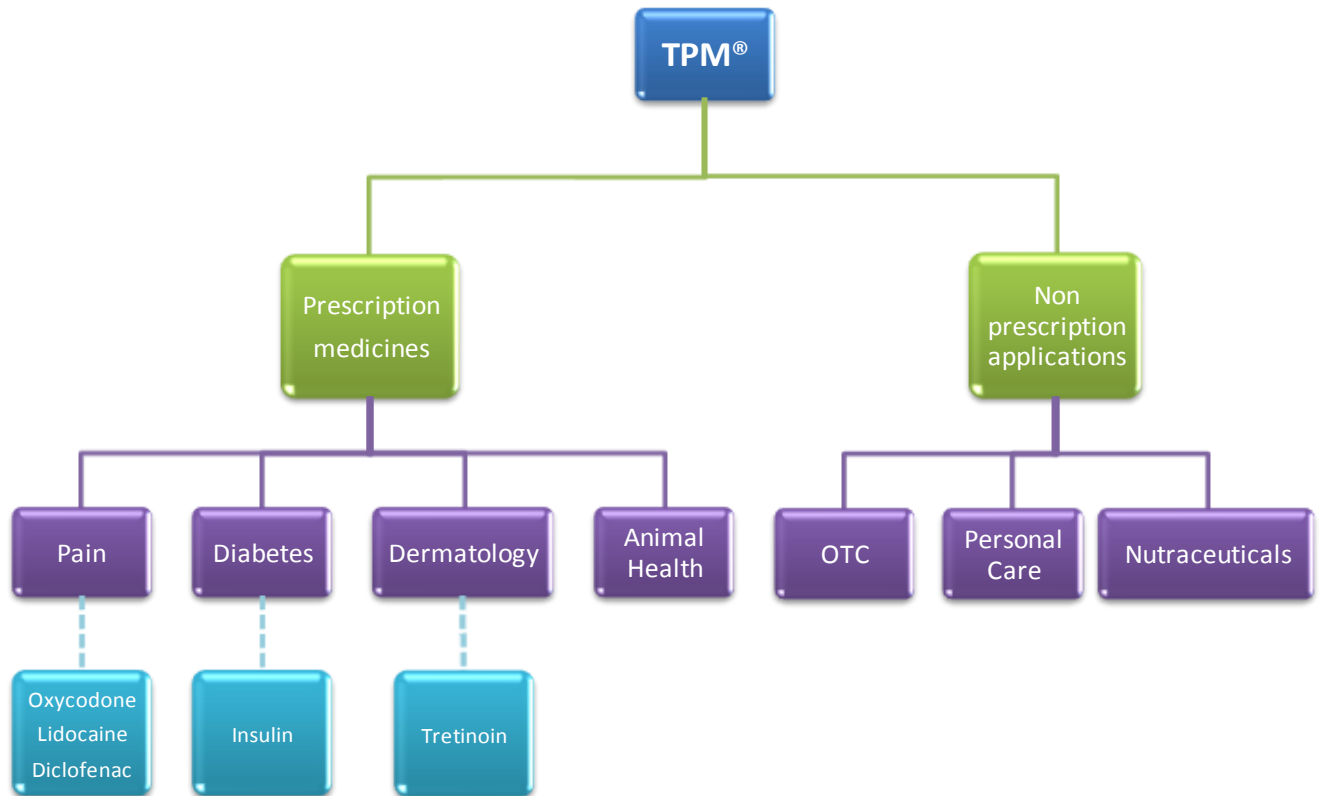
The key intellectual property revolves around the clinically validated transdermal and oral  $\alpha$ -tocopheryl phosphate mixture delivery platform first discovered in 2002. There are around 20 patent families protecting various aspects of the technology used in Phosphagenics' products with expiry dates varying from 2020-2031.

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<sup>2</sup> Generally Recognised as Safe – an FDA designation

<sup>3</sup> The TPM<sup>®</sup> nanoparticle system is a unique, ultra-flexible carrier with a complicated internal structure able to entrap drug molecules of interest.

Figure 1: Current Applications of TPM® Technology



### 3. KEY PRODUCTS IN DEVELOPMENT USING TPM<sup>®</sup>

#### 3.1 TPM<sup>®</sup>/Oxycodone Pain Patch

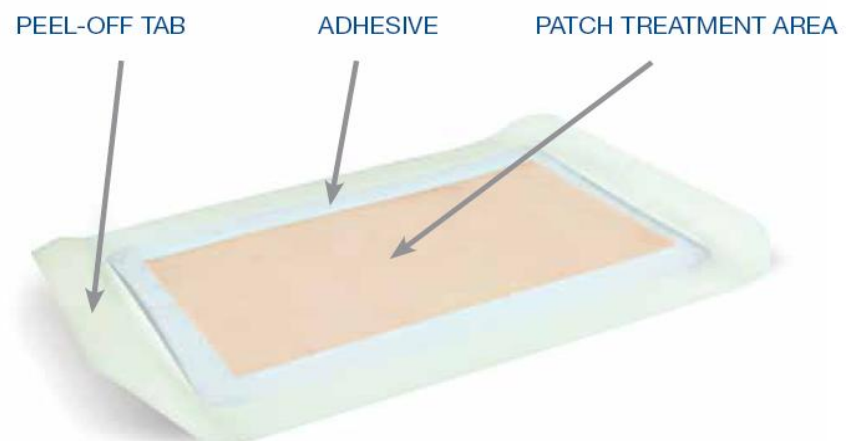
##### 3.1.1 Overview

POH is working towards the development of a product that will become the first to provide chronic pain sufferers with a patch that will provide sustained-release oxycodone into the bloodstream.

Oxycodone is an opioid derivative and has become the drug of choice of patients suffering from debilitating diseases such as cancer. The drug is currently administered orally or intravenously.

The oxycodone matrix patch being developed by POH that combines oxycodone with TPM<sup>®</sup> technology is the also the first transdermal system to successfully deliver therapeutic oxycodone plasma concentrations for the management of pain without causing sensitisation or irritation. The use of the oxycodone patch has the potential to provide sustained drug delivery over days, thus removing some of the peaks and troughs associated with oral treatments.

*Figure 1: TPM<sup>®</sup>/Oxycodone Pain Relief Patch*



*Source: Phosphagenics 2010 Annual Report*

##### 3.1.2 Clinical Studies

The company has conducted two successful Phase I studies in 2009 on its TPM<sup>®</sup>/oxycodone formulation.

The **first** study (Phase Ia) was an open-label, human Repeat Insult Patch Test (RIPT) that evaluated the skin response of 50 healthy participants. The study concluded that no erythema or sensitisation was observed.

A **second** study (Phase Ib), was undertaken in 20 healthy volunteers at the Royal Adelaide Hospital<sup>4</sup>. The main objective of the Phase Ib study was to compare the delivery profiles of two transdermal patch candidates containing TPM<sup>®</sup>, a matrix and a reservoir system, following

<sup>4</sup> The study was headed by Professor Guy Ludbrook, Principal Investigator for the study and the Head of Discipline, Anaesthesia & Intensive Care at the Royal Adelaide Hospital.

daily application over a 10-day period. Results from the study demonstrated that oxycodone plasma concentration increased throughout the entire 10-day dosing period after daily application of the matrix patch. Average plasma concentrations reached therapeutic levels and continued to rise daily during the 10-day period.

In addition, rapid drug elimination was evident following the removal of the final matrix patch on the 10<sup>th</sup> day of the study. Of the two transdermal patch candidates considered, POH decided to continue development of the matrix patch only, as its oxycodone delivery profile was much superior to the reservoir system. The matrix patch also had the greater potential to reduce drug abuse.

A **third** study, led by Professor Guy Ludbrook, was designed to identify the optimal dose of oxycodone required in a patch to deliver therapeutic blood levels, using the TPM<sup>®</sup>/oxycodone patch delivery system. In addition, the trial also examined the optimal duration that the TPM<sup>®</sup>/oxycodone patch should be left on a patient. The study compared the daily application of the TPM<sup>®</sup>/oxycodone patches of different oxycodone doses as well as comparing the application of the TPM<sup>®</sup>/oxycodone patches applied daily to the patches applied once per week<sup>5</sup>.

The study demonstrated that the extended dosing period of 14 days enabled steady state<sup>6</sup> delivery of Oxycodone into the bloodstream when applied **daily**. The weekly patch provided constant levels of oxycodone over seven days, producing blood levels suitable for less severe pain indications

### **3.1.3 Development Plans**

POH is currently working on the commercial development of the TPM<sup>®</sup>/oxycodone pain patch and has entered into an agreement with 3M for a commercial-scale patch manufacturing process. 3M is a leading patch developer and manufacturer of patched worldwide. Prior to the agreement with 3M, patch development had been carried out by POH in-house.

The commercial scale manufacture is expected to be completed in the 3<sup>rd</sup> quarter of 2011, at which point Phase II/III clinical trials will commence. POH is also expected to submit an IND application to the FDA in the 4<sup>th</sup> quarter of 2011.

Under the guidance of Professor Guy Ludbrook has assembled an international pain advisory board and regulatory consultants to plan the path forward into Phase II/III trials and commercialisation of the TPM<sup>®</sup>/oxycodone patch system.

### **3.1.4 Focus of Phase II/III Clinical Trials**

Phase II/III clinical trials will focus on safety over repeat exposure. POH are likely to use an osteoarthritis indication and assess parameters such as efficacy, blood levels and safety. The exact details of the trials will be finalised in consultation with the company's pain advisory board, who are all experts in the development of pain products.

<sup>5</sup> Each of the 40 subjects was administered with TPM<sup>®</sup>/oxycodone patches for 14 days either daily or once per week.

<sup>6</sup> Steady state occurs when drug concentrations in the blood stream remain constant over time and is a vital end-point for any sustained therapy.

### 3.1.5 Market opportunity for TPM<sup>®</sup>/oxycodone patches

The US is the largest and most commercially attractive market for pain drugs in the world. An estimated 75 million Americans experience acute pain each year. Opioids are the gold standard for pain treatment<sup>7</sup>. The total market value of prescription opioid sales in the US was US\$8.4 billion in 2007, accounting for over 70% of the global total. The opioid market in the US has grown on average by 13% each year since 2001.

Pain therapy is an area of high unmet medical need, and therefore provides many commercial opportunities. Demand for pain drugs continues to increase, fuelling the growth of a market that is expected to be worth US\$50 billion annually by 2020. With most types of pain still poorly treated, considerable investment is being made internationally in discovering novel approaches to treat pain, in particular those with fewer side effects and ones that will improve pain management (meaning shorter hospitalisation). Common adverse reactions in patients taking opioids for pain relief include: nausea and vomiting, drowsiness, itching, dry mouth, miosis, and constipation.

The current regulatory environment for opioids is one area of opportunity for POH's TPM<sup>®</sup>/oxycodone patches to gain market penetration. Opioids are highly regulated by authorities such as the FDA and the Drug Enforcement Agency (DEA) in the US, and the Therapeutic Goods Administration (TGA) in Australia. In January 2011, the FDA announced that it is asking manufacturers of prescription acetaminophen<sup>8</sup> combination products (such as Vicodin and Percocet) to limit the maximum amount of acetaminophen in these products to 325 mg per tablet, capsule, or other dosage unit.

The FDA believes that limiting the amount of acetaminophen per tablet, capsule, or other dosage unit in prescription products will reduce the risk of severe liver injury from acetaminophen overdosing, an adverse event that can lead to liver failure, liver transplant, and death.

Some US doctors already avoid prescribing pills that combine acetaminophen with narcotics like oxycodone (found in Percocet) and hydrocodone (in Vicodin). On June 30, 2009, an FDA advisory panel recommended that Percocet, Vicodin, and every other combination of acetaminophen with narcotic analgesics be removed from the market because of their contributions to an alleged 400 acetaminophen related deaths in the US each year, which were attributed to acetaminophen overdose and associated liver damage.

**It is worth noting that at this stage the POH patch is a single active patch, with oxycodone being the only active used.**

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<sup>7</sup> The market for opioid drugs can be broken up into drugs for the immediate relief of pain and drugs for the relief of pain over time (typically a number of hours).

<sup>8</sup> Otherwise known as paracetamol and is a widely used OTC analgesic (pain reliever) and antipyretic (fever reducer). High doses of acetaminophen are a leading cause of liver damage, and the panel noted that patients who take Percocet and Vicodin for long periods often need higher and higher doses to achieve the same effect.

## **3.2 AOP9604 – BodyShaper Cellulite Contour Crème™**

### **3.2.1 Overview**

The novel AOP9604 is a 16 amino acid peptide that is derived from a fragment of human growth hormone (hGH). The AOP-peptide is a patented anti-obesity compound that exhibits fat-reducing activity in the same way natural growth hormone regulates fat metabolism, without having any effect on growth, blood sugar or insulin resistance that can be evident with unmodified Growth Hormone.

Clinical studies found AOP to mobilise body fat by stimulating the process of lipolysis (the breakdown of fats), as well as inhibiting the formation of body fats from excess carbohydrates (called lipogenesis). POH has developed an easy-to-use topical cosmetic cream, which combines AOP with cosmetic actives (such as caffeine and forskolin<sup>9</sup>) and TPM<sup>®</sup> technology. This application targets the unwanted appearance of cellulite and also protects against the future appearance of cellulite by helping to make the skin appear less dimpled.

AOP9604 was developed by Melbourne-based biotechnology company Metabolic Pharmaceuticals from the late 1990s to a Phase IIb clinical study in 2007. Metabolic Pharmaceuticals subsequently changed its name to Calzada Ltd. The intellectual property for AOP9604 remains held by a fully-owned subsidiary of Calzada Ltd.

Metabolic Pharmaceuticals conducted Phase IIb clinical trials (536 patients) for AOP9604 as an anti-obesity drug. The results of the trials indicated that the drug failed to achieve a statistically significant weight loss in any dosage group after either 12 weeks or 24 weeks of treatment and that there was little overall weight loss despite a formal diet and exercise program that had been put in place for the trial. POH believe that by delivering the peptide topically into the skin, directly targeting the topical fat cells, is more likely to result in a visible effect.

### **3.2.2 Development Work Undertaken by Phosphagenics on AOP9604**

POH's decision to develop AOP9604 as a topical anti-cellulite cream using TPM<sup>®</sup> technology is supported by:

1. Results from the Phase IIb clinical trials that showed the drug had some efficacy in females who didn't diet or exercise well, suggesting that AOP9604 had a genuine capability to reduce fat levels.
2. Pre-clinical evidence that indicated that AOP9604 works well in regulating fat metabolism when it reaches the location of fat storage.
3. Oral delivery of the drug in Phase IIb clinical trials likely reduced bioavailability and may have resulted in protein denaturation in the stomach, which would have reduced the drug's activity. POH believe that TPM<sup>®</sup> technology can rectify the problem of drug delivery, as its delivery method is via the skin, thus avoiding the stomach, digestive system or blood stream. In addition, the size of

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<sup>9</sup> Caffeine has been shown to inhibit the process of fat deposition in fat cells. Forskolin is a naturally-occurring plant material that has been shown to activate an enzyme called adenylate cyclase, which reduces the effect of lipolysis.

the AOP9604 compound is within the range of molecules already delivered by the TPM<sup>®</sup> technology.

### 3.2.3 Initial Results from Independent Study

In October 2010, POH entered into a licensing agreement with Calzada Ltd for the launch of a cosmeceutical product that combines AOP9604 with the TPM<sup>®</sup> technology. Prior to entering into the licensing agreement, POH had already sourced the peptide from a low-cost manufacturer in Taiwan and formulated a developed a topical product using TPM<sup>®</sup>.

The product, launched in April 2011 as *BodyShaper Cellulite Contour Crème™*, is currently undergoing focus group trials in the US. The study is being conducted by AMA Laboratories Inc in New York on 30 women and involved morning and night application of the *BodyShaper Cellulite Contour Crème™* to the upper thigh of a single leg. The application area will be assessed over an 8-week period for any quantifiable changes in the visible appearance of cellulite, as well as skin hydration and elasticity.

After 28 days of application, the visible appearance of cellulite was significantly reduced by as much as 40% at the areas of application. Of the women in the study group, 86% reported a perceived improvement to the visible appearance of the bumps and dimples of their cellulite, while 96% also observed an improvement to skin firmness and smoothness and 93% saw an improvement in skin tightness. Over the course of the 28-day period, measurable skin hydration increased by 20% and skin elasticity increased by 5%.

### 3.2.4 Market opportunity for AOP9604

Current leading commercial cosmetic creams claiming subcutaneous fat reduction are typically not supported by any studies demonstrating efficacy. In this context, we envisage that a product with strong proof of efficacy such as AOP9604 would be able to quickly gain market share in a global market, particularly given the low cost of entry.

The existing cosmetics market is estimated to generate global sales in excess of US\$3 billion annually, for products that promise firming, toning or smoothing of the skin, as well as the reduction in the appearance of the 'orange peel' effect. Anti-cellulite products that are currently available generally have little, or no, clinical studies to support efficacy. (E.g. Revitol)

The market for cellulite-reduction devices in the US was more than US\$47 million in 2008 and projected to grow to US\$62 million by 2013<sup>10</sup>.

A substantial market has emerged in the US for anti-cellulite products. Obesity rates in the US among the highest in the world, with 68% of all US adults overweight or obese<sup>11</sup>.

<sup>10</sup> Source: Millennium Research Group

<sup>11</sup> Source: National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

## **4. OTHER PRODUCTS USING TPM<sup>®</sup> TECHNOLOGY**

### **4.1 Development of Anti-Psoriasis Treatment**

In February 2011, POH announced that it had entered into an agreement with an unnamed private dermatology company in the US to develop a prescription drug to treat psoriasis. The unnamed company has received approval from the US FDA for an Investigational New Drug (IND) application, clearing the path to commence a Phase I clinical study in the US. Psoriasis is a common chronic skin disease that affects about 2% of the population and is one of the most prevalent autoimmune diseases worldwide, with over 125 million sufferers.

The new product to be developed combines TPM<sup>®</sup> technology with an unnamed anti-psoriasis drug. *In vitro* studies demonstrated that this new formulation delivered the drug five times more effectively than delivery of the drug not using the TPM<sup>®</sup> technology.

Under the terms of the agreement, the dermatology company will pay for a Phase I clinical study in the US to evaluate the ability of the TPM<sup>®</sup> technology platform to improve delivery of the drug into the skin and increase efficacy. The Phase I study is expected to commence in the first half of 2011.

At the completion of the Phase I study, the dermatology company may exercise an option to license the TPM<sup>®</sup> technology for its anti-psoriasis drug. If the option is exercised, the dermatology company will conduct and pay for all clinical trials required to register the topical drug in the US, as well as pay POH milestone and royalty payments.

### **4.2 Development of Anti-Acne Treatment**

In April 2011, POH announced that it entered into the second stage of a development agreement with an unnamed global dermatology company to jointly develop a prescription drug to treat acne. The new product combines the TPM<sup>®</sup> technology with an unnamed anti-acne drug. Under the terms of the agreement, the dermatology company will pay for all development costs. The first phase of development will be to finalise the commercial product and establish its stability profile prior to entering clinical trial in the 4<sup>th</sup> quarter of 2011. The global topical acne product market is estimated to be worth over US\$2 billion per annum.

Major dermatology companies include Bayer Schering, Galderma (a joint venture between Nestlé and L'Oréal), GSK, Novartis, Merck, Sanofi-Aventis and J&J.

In April 2009, POH confirmed that Phase I clinical trials of confirmed that TPM<sup>®</sup> technology increased delivery of retinoic acid, with reduced irritation and higher tolerance levels, in comparison to Retin-A<sup>®</sup> - a leading commercial product used for the treatment of acne. Retinoic acid is the drug most commonly prescribed by dermatologists for topical treatment of acne and irritation is the most common adverse side effect that affects almost 90% of patients.

The ability of TPM<sup>®</sup> technology to achieve increased delivery while reducing skin irritation provides POH with an opportunity to create a product with market-leading potential.

### **4.3 TPM<sup>®</sup>/Insulin Product**

POH has undertaken work to develop a product that offers diabetes patients the world's first transdermally delivered and steadily released insulin over an 8-12 hour period. The TPM<sup>®</sup>/Insulin Product is targeting Type 1 and Type 2 diabetic patients that require regular glucose regulation by delivering a sustained insulin release in order to control and manage their diabetes.

In late 2008, POH completed a transdermal insulin human trial<sup>12</sup> that demonstrated that its TPM<sup>®</sup>/Insulin formulation safely delivered insulin into patients with Type 1 diabetes. In that trial, the insulin was delivered for the first time transdermally to patients without the use of device, typically injection or the more invasive pump system. TPM<sup>®</sup> technology has the ability to deliver insulin through the skin and into the blood stream, with the potential to reduce the number of invasive injections per day.

In December 2009, POH announced that its scientists completed dose optimisation of the insulin formulation, thus reducing substantially the amount of insulin required to achieve therapeutic dose. In addition, it was demonstrated that blood glucose levels in the majority of patients were lowered for the duration of the studies.

POH is currently assessing commercial opportunities for the product.

### **4.4 Cosmetic Products**

In early 2010, POH entered into an agreement with New York based company Métier Tribeca LLC for Métier Tribeca to market and sell a cosmetics range containing Phosphagenic's TPM<sup>®</sup> technology under the Le Métier Beauté brand.

For the first 12 months, Métier Tribeca sold 20,000 units from an initial launch of two TPM<sup>®</sup> cosmetics products and in January 2011, announced that it will launch a further eight new products into the New York market. The new range also uses the TPM<sup>®</sup> technology to enable superior skin diffusion, reduce skin irritation and enable a more effective application on the skin than the majority of other topical formulations currently available.

The new products are a luxury range and will be initially launched as a professional range, prior to being rolled out to leading department stores in the third quarter of 2011. Métier Tribeca will be responsible for the manufacturing costs, packaging, marketing and distribution of the products.

### **4.5 TPM<sup>®</sup> Technology to Fast Track natural-based formula targeting Mastitis**

POH has partnered with dairy research company Mastitis Management Australia (MMA) to utilise its TPM<sup>®</sup> technology to deliver a nature-based formula targeting mastitis. It is estimated that these two markets have about six million milk-producing cows. Given that industry authorities estimate that 15% of any given herd suffers from clinical or sub-clinical mastitis, about 900,000 cows in Australian and NZ would be affected.

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<sup>12</sup> Essentially a small-scale proof of concept trial

The new technology will aim to improve the bioavailability of key nutrients, to supplement diets where antioxidant levels may be low. By targeting cattle susceptible to mastitis, this may provide a benefit as part of a natural approach to help control mastitis within the herd.

By using the versatile TPM<sup>®</sup> delivery technology, Phosphagenics aims to provide superior benefits to farmers globally by reducing the downtime and lost revenue associated with expensive drug treatments with which each case of clinical mastitis is estimated to cost farmers at least \$200.

Independent dosing trials have determined that the antioxidants, when combined with TPM<sup>®</sup> have the ability to lower the somatic cell count (SCC) in diseased cows (a key indicator of infection) by up to 90% in four weeks.

The formulations were delivered to cows via a drench. POH are currently seeking to license the technology to a multinational for global distribution.

## **4.6 Hair Care Market**

In April 2011, POH announced that it signed a license agreement with a prestige New York hair care company (operated by Rodney Cutler) that will enable Cutler to use TPM<sup>®</sup> delivery technology to develop a new range of hair care products for the US, UK and Australian markets that will target the delivery of active ingredients into the scalp.

This is the company's first foray into the hair care sector, which is estimated to be worth US\$67 billion globally. The US, UK and Australian markets accounts for over 15% of the global market.

Cutler will be responsible for manufacturing, selling and distributing the products and will pay POH royalties on all sales. The first sales in the US from the new product range are expected in the 1<sup>st</sup> quarter of 2012, followed by a global distribution and rollout.

## 5. BOARD OF DIRECTORS

DIRECTOR	INTEREST IN POH	BACKGROUND
<b>Jonathan Addison</b> <i>Non Exec Chairman</i>	19,000 ord shares	<p>Mr Addison has over 30 years experience in the investment management industry, including wide experience in superannuation. Currently, he is the Investment Manager (formerly Fund Manager) of the Meat Industry Employee Superannuation Fund (MIESF), which is a nationally-operated self-administered industry superannuation fund.</p>
<b>Harry Rosen</b> <i>President &amp; Joint CEO</i>	~64.22m ord shares	<p>Mr Rosen is one of the founders of Betatene Ltd and Denehurst Ltd, two formerly ASX-listed companies which commercialised significant research and development. Betatene is the world's largest producer of natural beta carotene. After the purchase of Betatene Limited by Henkel Corporation, Mr Rosen served as Vice President, Corporate Development. As a Vice President of Henkel Corporation, he worked for a number of years in the US in the nutrition and health care industries.</p> <p>Mr Rosen has consulted to many technology companies assisting them with the commercialisation of new technologies. He has had significant experience in the areas of seed capital raising, stock exchange listings, taxation and corporate law.</p>
<b>Dr Esra Ogru</b> <i>Joint CEO</i>	~5.71m ord shares	<p>Dr Ogru joined the company in 2001 to lead the Research &amp; Development team and became a director of Phosphagenics in 2005. In 2009, she took on the role of Chief Operating Officer prior to her appointment as Joint CEO in April 2010.</p> <p>Dr Ogru has many years experience in the pharmaceutical and biotechnology industries working in development and senior management roles. She has over ten years of experience in the management and coordination of pre-clinical and clinical development of pharmaceutical products.</p>
<b>Don Clarke</b> <i>Non Exec Director</i>	30,000 ord shares;	<p>Mr Clarke, who was appointed to the Board of Phosphagenics in August 2010, has been a partner of law firm Minter Ellison since 1988. He serves in the Melbourne Private Equity &amp; Capital Markets group, predominantly advising ASX listed companies across a range of industries with emphasis on technology and manufacturing.</p> <p>Mr Clarke is also the Deputy Chairman of Webjet Ltd and a Director of Circadian Technologies Ltd. He previously served on the Board of Calzada Ltd (formerly Metabolic Pharmaceuticals Ltd).</p>

**Stuart James**  
*Non Exec Director*

NIL

Mr James has held a number of high profile executive positions during his career and has extensive experience in the oil, health, pharmaceutical and financial services sectors. Following a 25 year career with Shell, both in Australia and internationally, Mr James past roles have included Managing Director of Australian Financial Services for Colonial Group and Managing Director of Colonial State Bank (formerly the State Bank of NSW).

Mr James most recent executive role was as CEO of the Mayne Group, including Mayne Health and Mayne Pharma. He is Chairman of Pulse Health Ltd, Progen Pharmaceuticals Ltd, Prime Financial Group Ltd and a Non-Executive Director of Greencross Ltd.

**Dr Sandra Webb**  
*Non Exec Director*

0.11m ord  
shares;

Dr Webb is an experienced pharmaceutical professional with a strong track record of achievements in the commercial world of drug development. She previously held the position of pharmaceutical development adviser with Phosphagenics from February 2005 to June 2006 and rejoined the company as a non Executive director in August 2010. She is currently a director of Ground Zero Pharmaceuticals P/L and previously served on the Boards of AusBiotech Ltd, Amrad Corporation Ltd and Quintiles Ltd.

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