



### ▶ Message from the CEO

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#### MESSAGE FROM THE CEO



##### Dear Shareholders,

It is our pleasure to provide you with our first newsletter for 2010.

The previous 12 months have been a remarkable period for our company, and this year we expect to continue with our high profile programs and focus on the development and commercialisation of our products and technology.

We have raised our profile internationally, and our key programs are in clinical development in high value markets. We will continue our discussions with various pharmaceutical, OTC and personal care companies, including global players. We are aiming to progress these discussions to commercial arrangements, thereby maximising shareholder value.

##### In 2010, we will focus on:

- Clinical development of lead programs – oxycodone and insulin delivery systems
- Commercialisation of our pharmaceutical portfolio
- Increasing company profile in Australia and USA

Regards,

**Harry Rosen, CEO**

#### ABOUT TPM TECHNOLOGY

Transdermal delivery describes a process whereby a substance is transported through the skin and into the blood. Transdermal delivery is usually the preferred route for many molecules, including drugs, as it avoids first passage metabolism, improves patient compliance and can significantly reduce side effects.

Phosphagenics has developed a novel delivery platform known as TPM™ (Targeted Penetration Matrix). TPM™ has the ability to deliver both small and large molecules through the skin without causing disruption, irritation or damage. Depending on the molecule of interest, TPM™ formulations can be created to deliver molecules locally (into the skin) or transdermally (Figure 1).

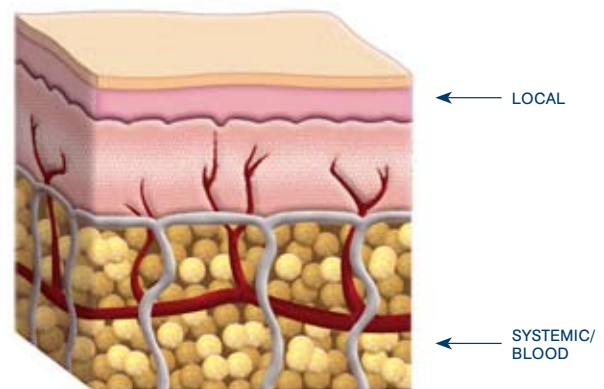


FIGURE 1: SKIN SECTIONS AND DEPTH OF DELIVERY

The TPM™ technology is versatile and can be formulated as a liquid, patch, spray, micro-emulsion and vesicular entrapment systems.

The vesicular entrapment system is a multi-layered, ultra-flexible carrier with tightly controlled size. These controls, and its unique properties, allow the TPM™ vesicles to be formulated in a range of sizes, from nanometer to micron diameters. These parameters can be used to control the rate and depth of delivery. TPM™ vesicular entrapment systems have been successfully used to deliver large molecules, such as insulin, through the skin and into the bloodstream.

## ▶ R & D Update

In the previous shareholders' update, we focused on the upcoming launch of our personal care and cosmetic products in the US and Australia. This newsletter focuses on our recent clinical studies as well as our prescription drug product portfolio. These are primarily insulin and oxycodone delivered transdermally.

Phosphagenics aims to become the first company in the world to deliver insulin, oxycodone and other opioids transdermally in a painless, user-friendly manner without irritation or disruption of the skin.

### PHOSPHAGENICS PAIN PATCH TO SATISFY GLOBAL UNMET NEED

Almost one in five Australians suffer chronic pain in their lifetime. A report by Access Economics estimates that chronic pain costs the Australian economy \$34 billion each year. There is a huge unmet need in sustained, controlled pain relief in Australia and the world; a need being tackled head-on by Phosphagenics.

Oxycodone is a drug readily administered for pain management globally and has wide market acceptance. It is the drug of choice for the management of chronic pain in patients suffering the effects of debilitating diseases, such as cancer and arthritis. Oxycodone is more potent than morphine, with fewer side effects, such as nausea. Currently, oxycodone is administered orally or intravenously. In 2007, sales of oxycodone were \$2,679 million globally.

In spite of its success, one of the key drawbacks of current oral opioid pain medications is that they do not maintain constant levels of the drug in the bloodstream. This often leads to 'peaks and troughs' resulting in 'breakthrough' pain. This effect results in the need to further medicate patients. A transdermal patch will reduce the side effects of oral medication and should help eradicate, or substantially reduce, the variability of the drug in the bloodstream, and, therefore, the occurrence of breakthrough pain.

Recent oxycodone clinical trial results demonstrate TPM's transdermal capability. The results demonstrated that daily application of the TPM™ oxycodone patch delivered therapeutic bloodstream levels of oxycodone in a reproducible, consistent and sustained manner.



The TPM/oxycodone patch has an excellent profile for treating chronic pain, as it can:

- Deliver sustained therapeutic blood levels of oxycodone
- Provide a rapid elimination of oxycodone after patch removal
- Eliminate skin irritation
- Reduce drug abuse compared to the oral product

Phosphagenics aims to be the first in the world to develop an effective and reliable oxycodone patch system, perhaps also for other opioids, and administer it to pain sufferers in a safe and patient-friendly manner. Presently, oxycodone is not available in a patch form.

The recent oxycodone Phase Ib trial was the subject of a prominent Channel Seven News report, which was televised across most states in Australia. It also gained international attention with media coverage in *Fox Business News* in the US, *BioSpectrum* across Asia, the highly influential website *StreetInsider*, as well as pharmaceutical trade papers both internationally and in Australia.

Phosphagenics is preparing to progress to the next stage of its oxycodone patch development. Under the guidance of Professor Guy Ludbrook, Professor of Anaesthesia, University of Adelaide, Phosphagenics has assembled an advisory panel of international pain experts to plan the Phase II and Phase III trials. Phosphagenics expects to commence its next clinical study during the second half of this year.

### INSULIN DELIVERY SET – HUMAN TRIALS READY TO GO

Diabetes is a chronic disease that occurs when the pancreas does not produce enough insulin (Type 1 diabetes), or when the body cannot effectively use the insulin it produces (Type 2 diabetes). Insulin is a peptide hormone that causes cells in the liver, muscle and fat tissue to take up glucose from the blood, storing it as glycogen in the liver and muscle, and stopping the use of fat as an energy source. More simply, insulin helps glucose (sugar) enter cells from the bloodstream to be converted into energy.

There is no cure for either Type 1 or Type 2 diabetes. All people with Type 1 diabetes require insulin treatment, while many suffering from Type 2 move progressively to insulin treatments to control blood glucose.

Phosphagenics' insulin formulation has now been incorporated into a patient-friendly transdermal patch, developed in-house, as a companion product to the in-house gel formulation. The company intends to re-enter human clinical trials within four months. Finding an alternative way to deliver insulin into the bloodstream in a sustained manner, without the use of injections, is one of the holy grails of the pharmaceutical industry. Currently insulin is administered through injections or pump systems.

Around 250 million people are living with diabetes today and this is expected to increase to about 380 million by 2025. Of these, over 90 per cent of patients have Type 2 diabetes. The global diabetes therapy market was about US\$26.3 billion in 2009 and is expected to grow to US\$34.5 billion by 2013.\*

Phosphagenics' TPM™ insulin delivery systems (patch and gel) have the potential to reduce the number of invasive injections, with the simple application of a patch or gel that delivers a basal level of insulin over a sustained period. Achieving basal level of insulin, the fastest growing segment of the insulin market, is currently provided by injections.

It is expected that the ageing population market is one that will embrace Phosphagenics' TPM™ system, as the

elderly often have difficulty with self-injecting or managing pump systems. These are the only two forms of insulin delivery currently available.

Additionally, insulin therapy is often indicated for patients with Type 2 diabetes. However, patients' fear of needles, doctors' resistance to initiating regimens of daily injections, or the ongoing expense of insulin pumps may prevent or delay this action. Transdermal delivery of insulin is much more patient-friendly than injected insulin, and could extend the current use of insulin treatments to this broader population in both developed and developing countries.

Earlier this year, Phosphagenics announced it had completed its insulin preclinical trials using its newly developed TPM™ insulin patch. Phosphagenics' scientists achieved excellent results in both optimising the insulin formulation and developing the insulin patch that incorporates the optimised formulation. Results have shown that insulin can be effectively delivered by the TPM™ patch system in diabetic animals, resulting in lower blood glucose levels. Planning for the return to human trials is well advanced.

\* *Espicom Business Intelligence Report (2009)*

## ▶ Update on Partnership

### PHOSPHAGENICS AND CSL KICK-START COLLABORATION

In late 2009, Phosphagenics began a collaborative feasibility study with CSL. This program was designed to assess the potential for delivering large proteins. Preliminary studies are underway at both Phosphagenics and CSL.



PHOSPHAGENICS

## ▶ IP Update

Phosphagenics continues to grow its patent estate, with the continued filing of new patent applications covering emerging developments in transdermal delivery, as well as progressing existing patent applications.

Phosphagenics currently has 180 live patents and patent applications, which are filed in all the major pharmaceutical markets.

## ▶ Corporate Update

With the positive Phase Ib data for oxycodone, Phosphagenics has commenced discussions with potential partners for the oxycodone patch, as well as the other pain products in development. Responses have been very encouraging and dialogue is continuing with several pharmaceutical companies.

Beyond the discussions on the oxycodone patch, Phosphagenics is actively continuing discussions relating to the insulin delivery program.

Phosphagenics' relationship with Le Métier de Beauté is expanding beyond the initial two Peau de Vierge products that were successfully launched in the US market in November 2009. The company is developing four additional cosmetic products with our formulators, Verdi Enterprises in New Jersey, progressively launching these in Australia and the US over the next 12 months.

Phosphagenics is in discussions with potential partners to develop over-the-counter (OTC) drugs, dermatological prescription drugs and animal healthcare products.

Phosphagenics' strategy involves accomplishing its goals in a financially responsible manner, while remaining focused on its primary objective of developing prescription drug products. Our objective is to increase shareholder value by taking full advantage of the company's proprietary platform technology, while using its superior capabilities of delivering products topically, thereby differentiating them from commercial products.

It is intended to expand into several markets and new product categories. The expansion into new product categories will be achieved by partnering the development with pharmaceutical or marketing companies similar to Le Métier de Beauté.

While Phosphagenics would typically undertake a substantial part of the research in each project, it is the company's position that these new projects must be funded by its partners. This approach minimises financial risk and provides a clear commercial outcome for the company through profit sharing, milestone payments and future royalties as products progress through the development pipeline.

In summary, the Phosphagenics approach is two-fold. Firstly, Phosphagenics remains focused on the products being developed in-house, including insulin and oxycodone. These involve relatively high financial risk, but also have the potential to substantially increase value to our shareholders. Secondly, and in parallel, Phosphagenics will leverage its technology by entering into new markets where products can be commercialised more quickly, providing free cash to fund development of pharmaceutical products.

Since September, Phosphagenics has renewed its public relations and investor relations programs in the US and Australia. Presentations have been delivered at the Rodman Renshaw Conference, the Maxim Conference, the One Med Forum and the Australian Life Sciences Forum in San Francisco. Presentations have also been given to a number of private and public investors.

## ▶ Our Focus in 2010

- Clinical development of lead programs – oxycodone and insulin delivery systems
- Commercialisation of our pharmaceutical portfolio
- Increasing company profile in Australia and USA