



Latest R & D News

▶ Phosphagenics Signs Agreement with Metabolic Pharmaceuticals Limited

Phosphagenics has announced that it has signed a collaborative research and option agreement with Metabolic Pharmaceuticals Limited (ASX: MBP).

Under the terms of the agreement, Phosphagenics may elect to license Metabolic's patented compound, AOD9604, for use as a cosmeceutical product aimed at reducing cellulite and subcutaneous fat. If Phosphagenics exercises its option to license the compound, it will pay Metabolic an undisclosed royalty on future sales of the product.

Metabolic developed AOD9604, a fragment of growth hormone, for the treatment of obesity. Its approach was based upon the normalisation of well-known hormonal and metabolic defects associated with both ageing and obesity.

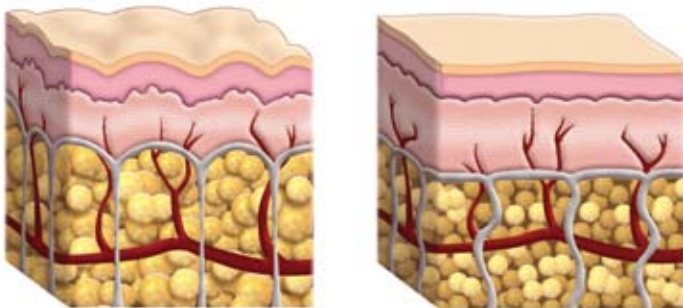
The collaborative research will focus on using Phosphagenics' proprietary TPM delivery technology to deliver AOD9604 transdermally. Phosphagenics' TPM technology has proven effective in delivering a range of both small and large molecules into and through the skin to target the local tissue around the site of application. The size of the AOD9604 molecule is well within the range of molecules already delivered by the TPM technology.

Previously, AOD9604 was administered orally. In 2007, Metabolic conducted a large human trial which showed that AOD9604 was safe and well tolerated but could not conclusively establish its efficacy.

Phosphagenics' novel approach is to use its patented TPM technology to topically deliver the compound to the subcutaneous fat directly, without having to travel through the systemic circulation to reach the targeted tissues. Phosphagenics and Metabolic believe that the biological properties of AOD9604 combined with the transdermal properties of TPM make for an ideal cosmetic product for the reduction of fat stores beneath the skin.

Launching a fat reduction cosmetic cream is consistent with the strategy that was outlined to shareholders at Phosphagenics' AGM in May 2009. These types of products do not require significant financial resources for research and development, and are not subject to the same stringent approval processes as drugs. Should the research prove to be successful, it is expected that a product will be ready for a market launch in the second half of 2010.

Dr Esra Ogru, COO of Phosphagenics, said, "The current leading commercial cosmetic creams aimed at reducing subcutaneous fat are backed by little scientific data or proof of efficacy. An efficacious, anti-fat cream should quickly command the global market. The low cost of entry into the personal care industry and the speed in which products can be launched into the market makes this industry extremely attractive."



▶ Before and after cross-section of cellulite





Message from the CEO

Dear Shareholders,

The previous twelve months have been a remarkable period for the company. Despite the Global Financial Crisis and one of the toughest financial markets in a century, Phosphagenics has continued to achieve its development and commercial milestones.

In June this year, we announced a research collaboration with global pharmaceutical company CSL, to develop needle-free drug delivery systems for a number of proteins using Phosphagenics' patented TPM delivery systems. Work on this project has already begun.

We are also pleased to be announcing our recent partnership with Metabolic Pharmaceutical Limited. Under the terms of the agreement we will be developing Metabolic's patented compound AOD9604, for use as a cosmeceutical product aimed at reducing cellulite and subcutaneous fat. The collaborative research will focus on using our TPM technology to deliver AOD9604 locally.

Launching a fat reduction cream is consistent with the strategy we outlined at our AGM in May 2009. These types of products do not require significant financial resources for research and are not subject to the same stringent regulations as drugs. Should the research prove to be successful, we expect that a product may be launched in the second half of 2010.

The signing of the agreements with CSL and Metabolic is an endorsement of Phosphagenics' drug delivery platform and fits perfectly with our commercialisation strategy.

Three significant clinical and pre-clinical trials have been completed this year, confirming that the TPM technology is on track as an entirely novel means of delivering drugs without the use of needles. Transdermal drug delivery is a global market worth over US\$3 billion and growing at a rate of 8.2% annually.

In January 2009, the company announced the successful completion of a Phase 2a human trial using the TPM system to deliver insulin in patients with Type 1 diabetes. The study

results confirmed the delivery of insulin in the target patient population. The product was found to be safe, well tolerated and efficacious. We are now in the process of optimising the formulation and reviewing the final form of the commercial product, likely to be a patch which would offer optimal control for patients.

In May we also announced the successful completion of pre-clinical studies incorporating the TPM gel and patch system to deliver the pain medication, oxycodone.

A month later we announced the successful completion of a Phase 1 clinical trial of transdermal oxycodone. In this study, conducted on 50 subjects, we showed that TPM/oxycodone does not induce irritation or sensitisation with repeat application. These are common side effects associated with topical use of opioids that have been a significant factor in preventing the commercialisation of a transdermal opioid product.

In what has been a very busy six-month period, the Company also announced an agreement with Métier Tribeca under which this US company will launch a premier line of cosmetic products using Phosphagenics' TPM technology. This is a major coup for an Australian company, giving us a significant road into the lucrative US cosmetic market.

The joint Phase 2 clinical trial with Nestlé has been completed. The study was designed to establish the efficacy of Phosphagenics' Phospha E[®] as a nutritional additive in the management of metabolic syndrome. Metabolic syndrome is a collection of disorders that occur together and increase the risk of developing Type 2 diabetes, stroke or heart disease. Phosphagenics and Nestlé are in the process of analysing all the clinical data. We will update the market as soon as the analysis is completed.

Our clinical trials with insulin and oxycodone are focused on delivering these drugs into the bloodstream.

► Highlights of First Half 2009

- Partnership deal with global pharmaceutical company, CSL
- Completion of insulin trial in patients with Type 1 diabetes
- Completion of pre-clinical studies, patch development and Phase 1 for oxycodone, demonstrating that in the TPM system there is no sensitisation and minimum irritation with repeat application
- Agreement signed with US cosmetics company, Métier Tribeca, to use TPM technology in its cosmetic lines
- Completion of Phase 2 clinical trial with Nestlé and the addition of Phospha E[®] as a nutritional additive in the treatment of metabolic syndrome


Message from the CEO

However, our TPM technology also lends itself to targeted delivery to local sites, such as skin and joints. We have had successful Phase 1 trials with lidocaine and diclofenac, which are commonly used to treat local pain, and tretinoin (vitamin A), which is used for the management of acne.

In summary, this year we focused on the development and commercialisation of our products and technology. The years of investment Phosphagenics' staff have put into our TPM technology have produced strong scientific evidence regarding the efficacy of our technology. Leveraging off our strong scientific background has allowed us to enter into the lucrative cosmetic and nutraceutical markets with proven products based upon clinical research. This business strategy offers high returns with minimum investment.

With a raised profile internationally and six programs in clinical development in high value markets – we will be focusing strongly in the next 12 months on further product development and commercialisation. We are in discussions with various companies, including global players, with the aim of progressing these discussions to commercial arrangements, thereby maximising shareholder value.

Regards,



Harry Rosen



► Phosphagenics Pipeline

	Research & Development	Pre-Clinical	Phase 1	Phase 2	Target Application
Drug Delivery – Transdermal					
Insulin	█	█	█	█	Diabetes
Oxycodone	█	█	█		Pain Management
Drug Delivery – Localised					
Lidocaine	█	█	█		Pain Management
Diclofenac	█	█	█		Pain Management
Drug Delivery – Dermal					
Retinoic	█	█	█		Acne Therapy
Drug Enhancement – Oral					
Phospha E	█	█	█	█	Metabolic Syndrome

Deal Opens the Door to Lucrative US Cosmetic Market

The latest deal done with US company Métier Tribeca demonstrates that Phosphagenics' patented technology is gaining international attention. In July, Phosphagenics granted Métier a license to manufacture and sell products using the TPM technology, with profits divided equally between both parties. Cosmetic products will be launched before the end of the first quarter of 2010 in the prestigious Neiman Marcus and Bergdorf Goodman retail stores.

The patented technology is a perfect fit for a major cosmetics firm. The TPM system delivers both small and large molecules into and through the skin in a non-invasive manner and with no irritation. This makes Phosphagenics' technology the perfect platform for

the delivery of active ingredients in personal care and cosmetic products.

According to Dr Esra Ogru, COO, there are a number of advantages to forming alliances with the cosmetic sector: "The low cost of entry into the personal care industry and the speed in which products can be brought to market shelves makes this a very lucrative and attractive market," she said.

The CEO of Métier, Mr Richard Blanch, added that his company is very excited about the Phosphagenics technology: "There are numerous applications in the beauty industry for this type of delivery technology. We are thrilled to be the first to bring it to the US marketplace," he said.



“The TPM system delivers both small and large molecules into and through the skin in a non-invasive manner and with no irritation”



► Breakthrough in Insulin Patch for Type 1 Diabetes

In January, Phosphagenics announced that its trial of transdermal insulin in patients with Type 1 diabetes had successfully reduced blood glucose levels in the majority of subjects treated.

The trial is a major breakthrough because it is the first time insulin has been delivered transdermally to patients with Type 1 diabetes without disrupting the skin or using a device such as a needle.

In this trial, the company used its patented transdermal TPM delivery technology to deliver insulin into the systemic circulation via the skin of patients with Type 1 diabetes. The increased insulin levels in the blood reduced blood glucose concentrations.

Since this small-scale proof-of-concept trial showed efficacy, the company has begun the next stage of its insulin formulation optimisation using an animal model of diabetes. This optimisation program is progressing very well, as Phosphagenics scientists have reduced the amount of insulin gel required to produce an efficacious response in animals and have improved the efficiency of absorption as well.

In parallel with the gel optimisation program, Phosphagenics will be conducting market research

among clinicians to determine the ideal final form of the final transdermal insulin product, which at present could be a gel, patch or spray. As we have recently completed development of a reservoir insulin patch, it is very likely that the final commercial product will be a patch and this development is expected to commence towards the end of the year.

Dr Esra Ogru, COO, said that the animal trials and patch development will determine the best formulation for clinical trials: "Once the optimised formulation has been incorporated into the patch and tested in animals, Phosphagenics will return to the clinic to conduct a dose ranging trial on humans with a superior product that will be in the final commercial form," she said.

There is significant market potential for a pain-free, convenient and cost-effective alternative to repeat insulin injections. Approximately 10 million people with Type 1 diabetes worldwide require insulin therapy, and all of these patients are required to inject insulin with needles. The worldwide market for all forms of insulin was over US\$7 billion in 2005 and is estimated at over US\$11 billion by 2011.





R & D Update

► Phosphagenics Signs Deal with CSL



In a major coup for the company, Phosphagenics has signed a research and option agreement with global biopharmaceutical company CSL Ltd, to evaluate the ability of its patented TPM delivery technology to deliver large products transdermally.

Despite their remarkable success, large protein drugs continue to suffer from significant drawbacks, especially with respect to their delivery (subcutaneously or intravenously injected). Improvements in protein drug delivery will increase patient compliance and expand many drug markets.

Phosphagenics will work with CSL to use the TPM delivery system to deliver a number of proteins. The company will receive undisclosed option, milestone and royalty payments should CSL pursue formulations that result from the collaboration.

► Oxycodone Trials: Taking the Pain out of Pain Relief

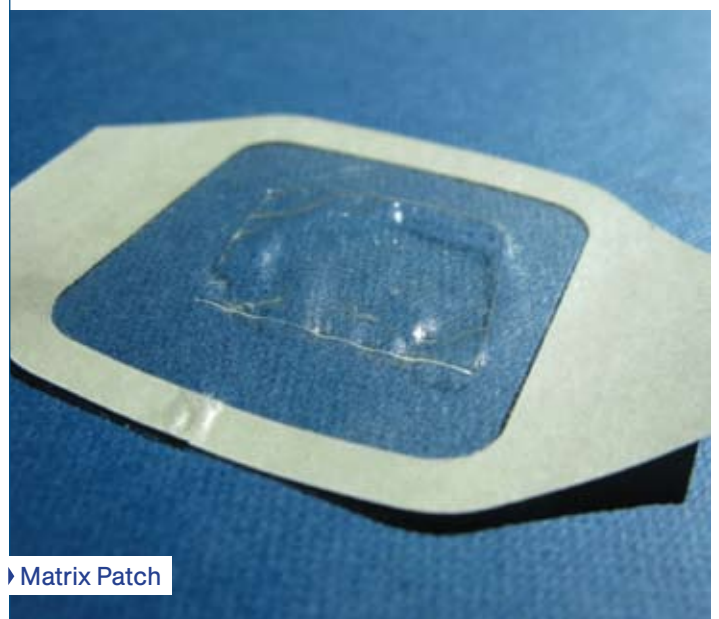
The company announced two major milestones in relation to its oxycodone program for pain relief. Oxycodone is a potent anti-pain drug similar to morphine. Pre-clinical trials of the patented TPM transdermal patch showed that systemic delivery of the pain medication, oxycodone, with this patch was markedly increased compared to the direct application of oxycodone gel to the skin.

Phase 1 trials of the oxycodone gel also found that repeated application did not result in redness of the skin or sensitisation, common side effects of the topical application of opioids or pain medication.

A Phase 1a efficacy and safety study began in early August 2009 with initial results expected by the end of September 2009.

Phosphagenics is on track to becoming the first company to produce a non-invasive technology that can deliver opioids transdermally into the systemic circulation via either a patch or gel – without causing sensitisation.

The opioids market is set to grow from US\$9.6 billion last year to US\$11.9 billion in 2018, so a slice of the 'transdermal pie' would be a significant target for Phosphagenics with its TPM delivery system.



► Matrix Patch