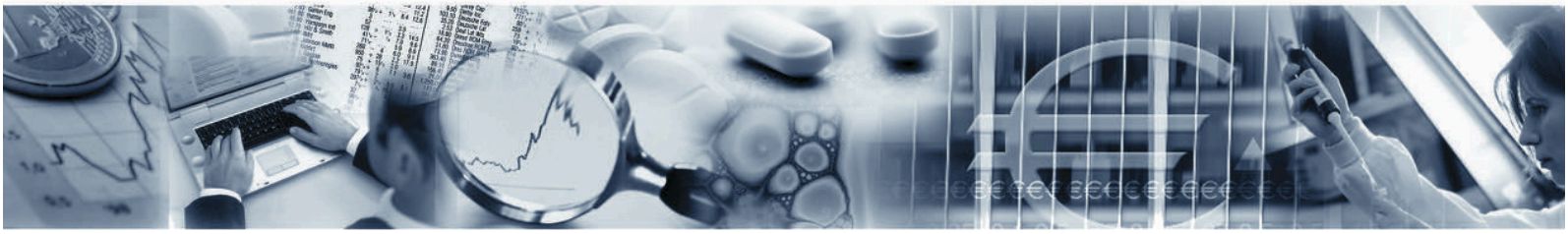

Research Note

Phosphagenics

Rising Phoenix

Chief Research Analyst

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Date: 28 September 2015

Name:	**Phosphagenics**
Country:	**Australia**
Price:	**AUD 0.014**
ISIN Code:	**AU0000ADOAC2**
Reuters Code:	**POH.AX**
Market Cap (AUD m):	**17.7**
EV (AUD m):	**1.9—(2.3)***
Cash & cash eq. (AUD m):	**15.8**
Shares outstanding (m):	**1,262**
Volume:	**1,814,230**
Free float:	**100%**
52-week Range:	**0.015-0.10**

***)R&D tax rebate owed but not yet received 2013-14 and 2015-16: 5.0 m**

AUD million (ending 31/12)	2013A	2014A	2015E
Total Income	2.158	2.505	2.200
Net (Loss)/Profit	(10.671)	(8.935)	(18.0)*
Net loss per share (cents)	(1.05)	(0.66)	1.43
R&D costs	3.383	3.777	2.85
Cash increase/(decrease)	(1.183)	(4.847)	(2.500)
Cash and marketable sec.	20.679	15.832	12.000

**) incl. AUD 8 million patents write off*

Executive Summary

- Phosphagenics (ASX: POH) is an Australia based drug delivery company that is commercializing various products within the pharmaceutical, cosmetics and animal health sectors, using its proprietary drug delivery system called TPM (Targeted Penetration Matrix). TPM is based on Vitamin E, that enhances the topical or transdermal delivery of active molecules. The lead products advancing through clinical trials are oxymorphone and oxycodone patches for the relief of chronic pain.

- Recently, the company went through a board and management restructuring process that resulted in a strategy to focus on the development of TPM via the ongoing clinical program in pain relief, the progression of their technology partnership with injectables, the build out of its animal health business and on consumer products in personal care. The company hopes to announce a number of partnerships in each of these businesses that will increase revenues both in the short and long run to propel the company into profitability. Next to the existing clinical programs using TPM, the focus is to also partner the technology with large companies selling into the mass market.

- Phosphagenics is currently recruiting patients for the ongoing " proof of concept" Phase IIa trial for the TPM Oxycodone patch. The trial is on track to be completed by the end of this year and provide top line results. The TPM Oximorphone patch is to be reformulated with the aim of lproducing a commercially viable patch that can proceed towards an IND for a US Phase II trial.

- In Animal Health, the company is using its TPM platform to improve the bioavailability and bioactivity of minerals and nutrients. In livestock, these products are expected to

enhance general health and immunity, increase live weight gain, and reduce the amount of antibiotics used.

- The company has a number of existing partnerships with large pharmaceutical companies for the commercialization and development of products Diclofenac Gel (Novartis, Themis Medicare), an antibiotic injectable (Mylan) and in Animal Health it licensed TPM to Integrated Animal Health (IAH). These partnerships will provide a growing stream of revenues for the short and long term.

- The market for chronic and acute pain management is a vast market with ongoing growth. Especially for chronic pain the use of opioids in the US is growing. In addition to the expansion of existing brands into new geographical regions, the uptake of new neuropathic pain products is expected to offset generic erosion, expanding the seven major market neuropathic pain sales from USD 2.4 billion in 2010 to peak sales of USD 3.6 billion by 2020.

- There are a number of news flow items to be expected in the next 6-12 months. The TPM Oxycodone patch program will reach a key milestone at the end of the ongoing Phase IIa clinical trial, which is targeted to complete by the end of 2015. Next year Phosphagenics expects to progress towards a Phase II trial with the TPM Oxymorphone patch in the US which could lead to the start of a potentially large partnership with a large pharmaceutical company.

- Based on our NPV valuation, we believe that Phosphagenics is substantially undervalued at the current share price of AUD 0.014.(AUD 18 million market capitalization). Using our valuation model, the Company's current total value should be AUD 80-100 million, or AUD 8.5c per share. This represents a substantial upside from the current share price.

Company Profile & Pipeline

Phosphagenics (ASX:POH) is an Australia based biotechnology company that discovers and develops novel ways to enhance the delivery, effectiveness, and/or tolerability of proven pharmaceutical, consumer and animal health products. Using a proprietary drug delivery system called TPM (Targeted Penetration Matrix), which is based on Vitamin E, Phosphagenics is developing a portfolio of novel and differentiated products. A strong global patent portfolio provides the company the basis to develop its pipeline consisting of products that improve human and animal health. In animal health the company is actively looking for further distribution of TPM containing products for the animal nutrition industry, for various farm animals. Currently it has licensed out the TPM platform for use in animal feed to Integrated Animal Health (IAH) for the development of high quality horse nutrition and for dairy cows in Australia and New Zealand.

The company's is active in the pharmaceutical market, and its strategy for this market is primarily to apply TPM to reformulate existing drugs, thereby leveraging accelerated regulatory pathways for drug approval (such as the 505(b) regulatory pathway in the United States). This enables the company to deliver innovative therapies to patients much quicker, and at lower cost, compared to standard drug development programs. In general terms, this is done by either enhancing the efficacy of existing topical or transdermal products, or establishing a new topical or transdermal route of administration for existing products that are currently marketed in either the oral or injectable form only.

Phosphagenics aims to enhance the efficacy of already approved drugs by increasing the amount or rate of drug absorption for an already available route of administration or developing products with a completely novel route of administration, thus exploiting new value for existing drugs. There is a growing need in many therapeutic areas for better delivery of active molecules and/or lower risk of complications and adverse events.

By applying TPM to generic drugs or drugs about to go off-patent, the company can utilize 505(b) or ANDA pathways for drug approval by the US FDA, enabling accelerated development and regulatory approval, with lower investment and much less risk than standard development programs. This reduces the risk profile of the company considerably and it keep its R&D expenditure relatively low.

Phosphagenics has several partnerships in place with large pharma companies both in human and animal health. Via its partnership with Novartis and Indian based Themis Medicare, the company is selling TPM Diclofenac Gel in India. Phosphagenics receives a royalty on sales of the products and supplies the TPM raw material. Last year Novartis India launched the Voveran TPM gel, and Themis launched the Instanac TPM gel. Phosphagenics is seeking commercial partners interested in marketing this product in other geographies.

The company also has a commercial arrangement with Mylan in relation to an antibiotic injectable. In this case TPM is used to enhance the solubilisation of the drug. Mylan took over this arrangement in 2013 as a result of the acquisition of Agila, the subsidiary of Indian company Strides. With Agila now well and truly part of the Mylan structure, progress towards commercialisation of this product is expected to accelerate this year. In the next 12 months we believe that more partnerships in relation to injectables may be announced.

In Animal Health Phosphagenics signed an agreement this year with Integrated Animal Health Pty Ltd (IAH) to sell feedstock (Feed-Mate) which included TPM for distribution in the UK and Ireland by distributor, Denis Brinicombe Group. The agreement specified amounts of at least AUD 550,000 at the beginning potentially growing to AUD 1.8 million per annum. Distribution will begin once the product has been registered and approved in the EU. Requirements for the EU registration are being assessed and registration is targeted for 2016. During the first half of 2015, Phosphagenics continued to receive earnings from other animal health arrangements with IAH and from product recently launched in New Zealand.

Phosphagenics' Pharmaceutical Pipeline

Product	Indication	Partner	Res./ Precl.	Phase I/II	Phase III	Market
TPM/ Diclofenac Gel	Pain	Novartis, Themis				**X**
TPM/Oxymorphone Patch	Pain (Opioid)	TBD		**X**		
TPM/ Oxycodone Patch	Pain (Opioid)	TBD		**X**		
TPM/ Tretinoin Gel	Dermatology	TBD		**X**		
TPM/ Diclofenac Patch	Pain (NSAID)	TBD	**X**			

One of Phosphagenics lead products in development is the TPM Oxymorphone Patch. Oxymorphone is an opioid, which is 3.5 times more potent than oxycodone and 7 times more potent than morphine. It has low bioavailability when delivered orally and is, therefore, an ideal candidate for transdermal delivery. Transdermal delivery of pain medications has considerable advantages over other delivery forms. The oxymorphone market of in excess of USD 600 million is dominated by Opana ER, an oral product manufactured by Endo Pharmaceuticals (2014 sales in excess of USD 300 million). It is approved by the FDA for the treatment of moderate to severe chronic pain. Phosphagenics is the first company globally to deliver therapeutic levels of oxymorphone via the transdermal patch. The overall amount of oxymorphone in a 72 hour transdermal patch is considerably less than the equivalent amount of Opana ER and although it still needs to be corroborated via a clinical trial, the dramatic reduction in the amount of oxymorphone that is dispensed to a patient is expected to reduce abuse potential. This would offer Phosphagenics a distinct competitive advantage. The FDA and DEA continue to monitor

opioids for abuse potential, and along with dozens of states, have made significant efforts to curb overprescribing of these drugs. Many manufacturers have remade some of the commonly prescribed opioids into abuse deterrent formulations. Yet, despite the major risks associated with their use, opioids remain the most effective and widely prescribed pain medications available in the US.

In May, Phosphagenics completed a review of its **TPM Oxymorphone patch** development program using specialist external consultants. On the back of previously announced clinical trial results showing that the TPM Oxymorphone patch can deliver blood levels of oxymorphone corresponding to the therapeutic levels seen with oral dosing, a further three critical path non clinical studies have now been completed. These studies assessed the "development and commercial readiness" of the patches made during the recently completed technical transfer process. The review of these non-clinical trials has concluded that additional specialized formulation work will need to be completed before the patch can be progressed further in the clinic. The Company will shortly engage an external group with expertise in patch development for this process.

In order to obtain an IND for the planned US Phase II trial, Phosphagenics will need to successfully complete several key development tasks including:

- technical transfer and scale-up of the GMP TPM Oxymorphone patch manufacturing process to a US patch manufacturer;
- successful manufacture of clinical and preclinical patch supplies;
- dermal toxicity studies on the US manufactured patch in a non-rodent animal model;

- TPM Oxymorphone patch stability study;
- Pre IND meeting with the FDA;
- collation of all available applicable data in an IND application; and
- further human PK characterisation clinical studies in Australia.

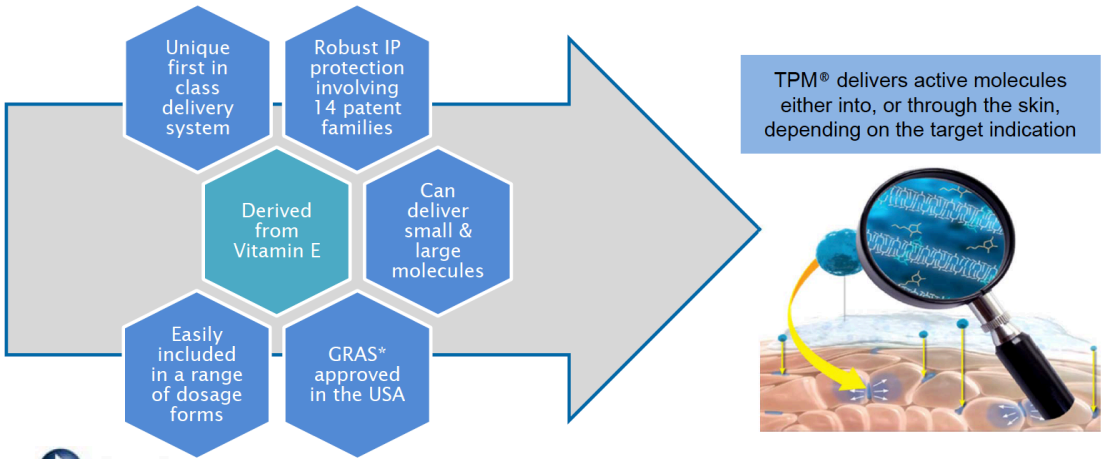
The **TPM Oxycodone patch** is currently in a proof of concept Phase IIa post-herpetic neuralgia (PHN) trial. Patient screening for the trial began early in 2015 and is continuing. First dose was announced in April and, to date, over 75% of candidates have been recruited. The trial is on track to complete and provide top-line results by the end of the year. PHN is a complication of shingles, which is caused by the chickenpox (herpes zoster) virus. Most cases of shingles clear up within a few weeks. But if the pain lasts long after the shingles rash and blisters have disappeared, it's called postherpetic neuralgia or PHN and affects nerve fibers and skin. The burning pain associated with PHN can be severe enough to interfere with sleep and appetite. The risk of PHN increases with age, primarily affecting people older than 60.

TPM Platform: Improved delivery method

Phosphagenics' core activities revolve around its proprietary delivery technology platform TPM: Targeted Penetration Matrix. The abbreviation TPM also stands for 'tocopheryl phosphate mixture' as it is composed of two different forms of phosphorylated Vitamin E (mono-a-tocopheryl phosphate, TP & di-a-tocopheryl phosphate, T_2P). Phosphagenics discovered that TP is a naturally occurring form of Vitamin E, present in animal tissues and plants. Whereas Vitamin E is an oil with very poor solubility in water, the addition of a phosphate group makes the TPM molecules soluble in both water and oil. Because TPM is built from Vitamin E, it is able to soothe the skin and reduce irritation that may be caused by the active ingredients that it delivers (e.g., tretinoin). Other delivery systems, such as those based on liposomes, are built from inert phospholipids and/or surfactants. Unlike TPM, their role is purely one of delivery, and they do not have any intrinsic properties of reducing irritation.

The application of medications to the skin to ease ailments is a practice that has been utilized by humankind over the millennia and has included the application of poultices, gels, ointments, creams, and pastes. These applications were primarily intended for a local topical effect. The use of adhesive skin patches to deliver drugs systemically is a relatively new phenomenon.

The first adhesive transdermal delivery system (TDDS) patch was approved by the Food and Drug Administration in 1979 (scopolamine patch for motion sickness). Nitroglycerine patches were approved in 1981. This method of delivery became widely recognized when nicotine patches for smoking cessation were introduced in 1991.



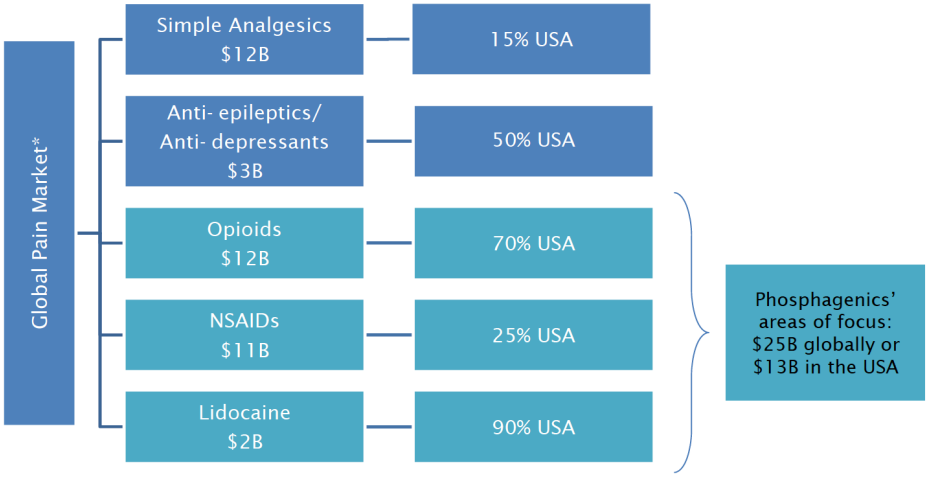
Source: Phosphagenics

A transdermal patch is a medicated adhesive patch that is placed on the skin to deliver a specific dose of medication through the skin and into the bloodstream. Often, this promotes healing to an injured area of the body. An advantage of a transdermal drug delivery route over other types of medication delivery such as oral, topical, intravenous, intramuscular, etc. is that the patch provides a controlled release of the medication into the patient, usually through either a porous membrane covering a reservoir of medication or through body heat melting thin layers of medication embedded in the adhesive. The main disadvantage to transdermal delivery systems stems from the fact that the skin is a very effective barrier; as a result, only medications whose molecules are small enough to penetrate the skin can be delivered by this method. A wide variety of pharmaceuticals are now available in transdermal patch form.

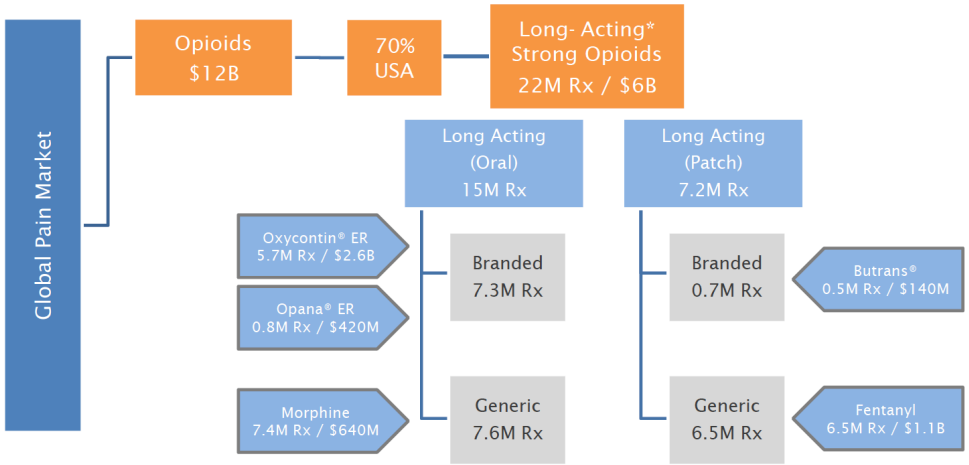
Opioids for chronic pain: vast growing market

Pain is a disabling symptom that can occur at any point in the course of an illness. Since pain considerably affects day to day life, its management offers considerable challenge for physicians. Inadequate pain control remains a major problem across the world. Pain relief medications are dominated by NSAIDs followed by opioids. Long acting opioids are used in the relief of moderate to severe pain, which require treatment for several days. Opioids are prescribed when pain cannot be adequately controlled with an NSAID.

All NSAIDs/Cox-2 inhibitors have cardiovascular and renal side-effects, and the older NSAIDs have severe gastrointestinal ones too. Therefore in cases of acute and chronic pain, opioids continue to be the mainstay of therapy. In 2013, the global opioids market was approximately USD 12 billion, representing a compound annual growth rate (CAGR) of 2.4% between 2002 and 2010. By 2017, the global opioids market is forecast to reach USD 13.2 billion, indicating a CAGR of 2.8% between 2010 and 2017. The market for pain management drugs is focused on enhancement of available dugs with the development of extended release formulations and drug combinations.



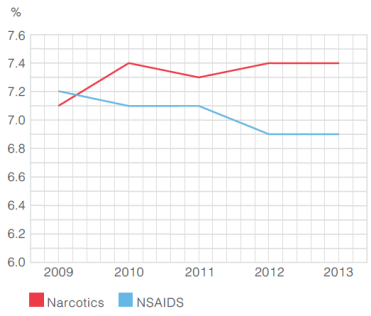
Opiate pain medications, also known as opioids, are one of the most controversial classes of prescription therapy. These medicines are most effective in providing relief to patients suffering from severe pain; however, their extremely addictive properties pose a serious risk to patients, and make them prone to misuse and abuse. Opioids, such as codeine, morphine, OxyContin (oxycodone HCl), and Vicodin (hydrocodone bitartate and acetaminophen), work by blocking pain signals to the brain. Unlike non-narcotic pain treatments (ibuprofen, acetaminophen, aspirin, naproxen), most opiates do not have a maximum clinically safe dosage limit. Over time, the body can build up a tolerance to the medication, so patients often require an escalation in the dose or strength of the medicine in order to effectively treat chronic pain and achieve the same level of pain relief. However, high doses of these drugs increase side effects and complications, as well as raise the risk of addiction and overdose. Physicians often prescribe opioids when non-narcotic medication is ineffective, or in conjunction with other painkillers. The most common conditions treated with opioid pain medications include cancer, back pain, osteoarthritis and neuropathic pain.



The Food and Drug Administration (FDA) and the Drug Enforcement Agency (DEA) closely regulate current opiate pain medications and classify them as controlled substances. Prescription rates for opioids increased dramatically in the past two decades after the government and medical organizations pushed for greater progress in pain control and set new guidelines expanding the use of opioids. While America claims less than 5% of the world's population, it consumes roughly 80% of the world's opioid supply. In fact, according to IMS Health, Vicodin and non-branded hydrocodone combination painkillers are the most commonly prescribed drugs in the country.

Older Americans who were taking only opioids for pain treatment had a significant increase in prevalence of use, up 4.5% from 2009 to 2013. During that same timeframe, the number of seniors (65+) using only NSAIDs (nonsteroidal anti-inflammatory drugs), and not opioids, declined by 5.1%. This shift away from NSAIDs to opioids occurred after a change in clinical guidelines in 2009 stating that narcotic painkillers are a safer choice for the treatment of chronic pain in the elderly given the adverse events associated with NSAIDs including gastrointestinal bleeds, kidney problems, and cardiovascular risks.

Prevalence of longer term opioid use
versus
longer term NSAID use in seniors



Source: The Express Scripts LAB

Animal Health: Reducing use of antibiotics

One of the outcomes of the recent formulated strategy is a stronger focus on animal health. Phosphagenics has utilized TPM to improve the bioavailability and bioactivity of minerals and nutrients. In food chain animals, these products can enhance general health and immunity, increase live weight gain, and reduce the amount of antibiotics used. Some of these TPM containing animal feeds and supplements are available in several countries. Phosphagenics is actively looking for further distribution of TPM containing products for the animal nutrition industry, for various food chain species and has indicated that it will undertake a series of trials to provide data to help facilitate future partnerships.

Antioxidants, such as vitamin E, play an important role in supporting immune function and health in dairy cattle with susceptibility to infections such as mastitis being linked to significant drops in vitamin E / antioxidant levels. Mastitis is inflammation of the mammary gland, primarily caused by bacterial infections. The pathological consequence in dairy cows is tissue damage, reduced milk yield, and changes in milk composition. Although mastitis is a multifactorial problem, herd management techniques (including nutrition) have been identified as significant in influencing the incidence of mastitis.

Each incidence of mastitis costs a farmer about USD 200 per cow, with 70% of that cost due to lost milk production as a result of high somatic cell count (SCC) and/or antibiotic use. At any one time, approximately 15% of a herd is estimated to suffer either clinical or sub-clinical mastitis. Antibiotics are the frontline treatment, however their use results in mandatory withdrawal periods for milk and meat production. Non-antibiotic alternatives are therefore of significant interest, both to dairy farmers and public health; in addition to providing a cost incentive to farmers, non-antibiotic treatments could improve consumer and regulator confidence by reducing the overall usage of antibiotics in food chain animals.

Analyst: Marcel Wijma MSc

Marcel Wijma, Chief Research Officer and managing partner, has a longstanding history in financial biotech research. After selling Van Leeuwenhoeck Research (VLR) to SNS Securities in 2006, he established an award winning analyst team in biotech/life sciences at SNS Securities. In 2009, Marcel was awarded by Financial Times/Starmine as being one of the Top-3 biotech analysts in Europe. Later that year, Marcel purchased VLR from SNS Securities after which the company was reconstituted. At VLR, he leads the professional VLR research organisation, which is augmented by selected external financial researchers with a specialisation in Life Sciences. Mr. Wijma has a Masters degree in Financial Economics from Erasmus University in Rotterdam.