



Initiating Coverage Report

Phosphagenics

Rising from the ashes



Chief Research Analyst **Marcel Wijma MSc** +1 (917) 460 6185 (US) +31 (6) 8489 2954 (NL) +61 (0) 426 4349 240 (AU) <u>m.wijma@leeuwenhoeck.com</u> http://www.leeuwenhoeck.com



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Name	:	Phosphagenics
Count	ry:	Australia
Price:		AUD 0.008
ISIN Co	ode:	AU000000POH7
Reuter	rs Code:	POH.AX
Marke	t Cap (AUD m):	10.1
EV (AL	JD m):	-9.9—-12.4 *
Cash 8	k cash eq. (AUD m):	20.0
Shares	outstanding (m):	1,262
Volum	e:	3,624,240
Free fl	oat:	100%
52-we	ek Range:	0.01-0.08
*)R&D t	ax rebate owed but not yet received	2015-16: 2.5 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	3.777	3.383	2.85	
Cash increase/(decrease)	(1.183)	(4.847)	(1.500)	
Cash and marketable sec.	20.679	15.832	14.300	

*) incl. AUD 8 million patents write off



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Executive Summary

Phosphagenics (ASX: POH) is an Australia based biotechnology 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, and it enhances the topical, transdermal, and oral delivery of active molecules. The lead products advancing through clinical trials are oxymorphone and oxycodone patches for the relief of various types of chronic pain.

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- Last year, the company has gone through a board and management restructuring process that has resulted in a strategy to focus on the development of TPM[®] via the ongoing clinical program in pain relief, the progression of an ongoing technology partnership in injectables, the build out of its animal nutrition business, and maximizing the usage of Vital ET® in personal care. The company hopes to develop a number of partnerships across these businesses that will increase revenues both in the short and long run, and propel the company into profitability.
- Phosphagenics recently announced results of the "proof of concept" Phase IIa trial for the TPM[®]/Oxycodone patch in postherpetic neuralgia (PHN). The trial did not show that locally delivered oxycodone reduce pain caused by PHN. However, the trail did demonstrate that the patch was effective in drug delivery. The TPM[®]/Oxymorphone patch, which completed a couple of successful Phase I studies, is to be reformulated with the aim of producing 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, when added to animal feed. In livestock, TPM's ability to enhance the bioavailability of feed is 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 companies for the commercialization and development of products, including Vital ET® for cosmetics (Ashland), the TPM®/Diclofenac gel (Novartis, Themis Medicare), and TPM®/Daptomycin (Mylan). These partnerships will provide a growing stream of revenues for the short and long term.
- There is a large and growing global market for chronic and acute pain management, and there continue to be several unmet needs. 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.
- Based on our NPV valuation, we believe that Phosphagenics is substantially undervalued at the current share price of AUD 0.007 and is trading heavily below cash. Using our valuation model, the Company's current total value should be AUD 100-115 million, or AUD 7.9-9.0c per share. This represents a substantial upside from the current share price.

Company Profile

Phosphagenics (ASX: POH) is a biotechnology company, headquartered in Australia, 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 conducting additional studies to assess the value of TPM as a feed additive, and 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 the development of high quality horse and dairy cow feed additives in Australia and New Zealand to Integrated Animal Health (IAH).

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Phosphagenics has several partnerships in place with large pharmaceutical companies. 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 called Daptomycin. In this case, TPM[®] is used to enhance the solubility and stability 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.

Business Strategy: Reformulating Existing Drugs with TPM

The company's core focus is the pharmaceutical market, and its strategy for this market is to apply TPM® to reformulate existing drugs, thereby leveraging accelerated regulatory pathways for drug approval (such as the 505(b)(2) regulatory pathway in the United States). This enables Phosphagenics to deliver innovative therapies to patients much quicker, and at lower cost, compared to standard drug development programs. In general terms, the company does this 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)(2) 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.

In October 2015, Phosphagenics announced a restructuring of its businesses that resulted from its strategic review. Moving forward, Phosphagenics will focus its resources on delivering the following priorities:

- Human Health and Nutrition business:
 - Phase II clinical development of the TPM®/Oxycodone patch for PHN (recently published),
 - Reformulation of the TPM[®]/Oxymorphone patch, and
 - Development of the TPM[®]/Daptomycin injectable with Mylan.

The agreement with a major manufacturing company for the initiation of the reformulation of the TPM[®]/Oxymorphone patch are targeted for 2016Q1.

- Animal Health and Nutrition business:
 - A comprehensive program involving multiple proof of concept studies across multiple species is planned for 2015-16.





The program is designed to provide valuable proof of principle for TPM[®] as a feed additive, and also the appropriate data to satisfy the requirements of both regulatory agencies and potential partners. Recently, Phosphagenics announced that a second swine study targeting meat quality and feed efficiency was initiated in December. This study follows-on from the first successfully completed weaner (young) pig that reported positive results and showed that TPM outperformed standard Vitamin E as feed additive. The outcomes of these studies have been designed to be both commercially relevant and provide the necessary information required for prospective commercial partners to assess the value of TPM[®] across the production lifespan of pigs. The results for the grower/finisher pig study is expected in 2016Q2.

- Bulk Production and Personal Care business:
 - Development of a new reactor to upgrade Phosphagenics' manufacturing facilities in anticipation of increased demand in 2016.

TPM: Better Delivery, Higher Efficacy

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The core of Phosphagenics is its proprietary TPM[®] delivery technology. The abbreviation TPM[®] 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, T₂P). 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 amphiphilic, meaning that they have solubility in both water and oil. This is important because the skin has both oil and water layers. Therefore, TPM[®] has increased solubility within the skin compared to standard Vitamin E, and is able to diffuse more efficiently.



Phosphagenics' Pharmaceutical Pipeline





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 2015, 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 nonclinical studies have now been completed. These studies assessed the "development and commercial readiness" of the patches made during the technical transfer



process to a US based contract manufacturing organization (CMO). The review of these nonclinical trials concluded that additional specialized formulation work would need to be completed before the patch can be progressed further in the clinic. In October 2015, the company entered into a development agreement with tesa Labtec GmbH, the German transdermal formulation specialists, to undertake the continued development of its transdermal TPM®/Oxymorphone patch.

Once the patch is reformulated, 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 TPM[®]/Oxymorphone patch manufacturing process to a US patch manufacturer;
- Successful manufacture of clinical and preclinical patch supplies;
- Dermal toxicity studies on the patch in a non-rodent animal model;
- A TPM[®]/Oxymorphone patch stability study;
- A 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 objective is to build on the work done to date and create a transdermal patch product with suitable characteristics for development through to commercialisation. Once formulated, the patch will then be progressed towards an Investigational New Drug (IND) application with the US FDA.



TPM[®]/Oxymorphone patch offers clear advantages

Compared to competitive products, the TPM[®]/Oxymorphone patch has clear advantages. It demonstrated clinically efficacious drug levels and good tolerability. In animal tests, TPM[®] appeared to overcome oxymorphone's previous problems with dermal irritation and sensitization. With the agreement with tesa Labtec, we expect the completion of a commercial patch this year.

Feature	Oral	TPM/Oxymorphone Patch
Breakthrough Pain	High Potential	Low Potential
Convenient Dosing	6x in 72 hours	1x in 72 hours
PK Profile	12 to 24 hours peaks and troughs,	Stable and moderate levels over 72
First Pass Metabolism	High	Bypassed
Reduced Drug Load	Up to 240mg	< 60mg
Need to Supplemental Medication	Moderate	Low
Risk of Accidental Overdose	High	Low
Constipation & Adverse CNS Effects	High Potential	Low Potential





Outcome Phase IIa TPM/Oxycodone shows effective drug delivery

Recently results of a proof of concept Phase IIa trial in patients with pain from post-herpetic neuralgia (PHN) with the **TPM®/Oxycodone patch** were announced. The Phase IIa trial was a randomised, double-blind, vehicle-controlled crossover study designed to assess the efficacy, safety and patch performance of Phosphagenics' topical TPM®/Oxycodone patch. Twenty-eight PHN patients suffering moderate-to-severe pain were randomised to the study, with 25 patients meeting the criteria for assessment in the primary endpoint. Each patient received a three-day treatment with both the TPM® /Oxycodone patch and the equivalent TPM® /vehicle control patch, separated by a washout period of 10 days. The primary endpoint compared the mean reduction in average Numeric Pain Rating Scale (NPRS) score over days two and three of each patch application period. The NPRS is an 11-point scale (0-10) that allows patients to grade the intensity of pain they have experienced over the past 24 hours.

The trial demonstrated that the TPM®/Oxycodone patch itself performed well in the older PHN patient population, maintaining the oxycodone delivery profile established in prior Phase I clinical studies on healthy volunteers, with:

- Good three-day adhesion characteristics in line with expectations for a commercial patch;
- Excellent skin tolerability, with minimal dermal irritation;
- Good drug delivery with minimal (sub-therapeutic) systemic exposure to avoid opioid side effects;
- An attractive side effect profile similar to the placebo/vehicle patch, without evidence of classical opioid side effects associated with oral dosage forms (ie: nausea, constipation, sedation, etc).



Despite the patch performing well and delivering oxycodone directly to the site of perceived pain, no statistically significant difference in pain relief was observed between the treatment and vehicle patch across the test population. PHN is recognised as a complex and problematic disease to treat and recent population studies in patients with PHN have shown that specific patient sub-groups can display different pain patterns and different responses to common therapies. This may explain why in a broad patient population a drug with a single specific mechanism of action may only show benefit in a subset of patients. In the current study, a posthoc subgroup analysis suggests that the TPM®/Oxycodone patch may in fact provide greater analgesia for a specific sub-group of PHN patients - with resultant reductions in NPRS scores of - 1.17 (+/- 0.540) for the TPM®/Oxycodone patch and -0.11 (+/- 0.320) for the vehicle control. The Company is continuing to analyse the data to more fully understand this result and this subgroup, and is working with key opinion leaders to determine the implications of this finding for the management of pain in specific PHN sufferers, as well as other, nonneuropathic models of local pain.

The TPM®/Oxycodone patch successfully met its performance objective; delivering oxycodone into the local tissue with minimal systemic exposure and an adverse effects profile similar to placebo. This is very important as it supports the commercial potential of our technology and the patch itself.

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

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.



Unlike most other personal care products, which sit on the surface of the skin, scientific testing shows that TPM[®] Delivery Technology absorbs further into the skin. Vitamin E in Phosphagenics' skin care products is in the form of tocopheryl phosphate, while Vitamin E in other brands' skin care products is in the form of tocopheryl acetate. The figure on the next page shows that the TPM[®] absorbs up to 4x greater than tocopheryl acetate into the epidermis, and up to 9x greater into the dermis. What this means is that TPM[®] enhances the delivery of active cosmetic ingredients into the skin.





The figure below shows results comparing the absorption of key skin care ingredients in formulations with TPM[®] and without TPM[®] (Franz Cell in vitro testing on human skin). TPM[®] delivered up to 5 times more forskolin (which helps optimize the appearance of skin tone) into the skin, and up to 2.5 times more caffeine (which provides a visible toning effect to the appearance of skin) into the skin.





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.

Advantages and Disadvantages of Transdermal Drug Delivery

There are biological advantages to delivering drugs through the skin:

- Transdermal delivery avoids the stomach environment where the drug can be degraded and rendered ineffective or where it can cause unpleasant gastrointestinal symptoms for the patient.
- Transdermal delivery avoids the first pass effect where active drug molecules can be converted to inactive molecules or even to molecules responsible for side effects.
- Transdermal drug delivery provides steady plasma levels. When a patch is applied that lasts for 24 hours, or even 7 days, once steady state is reached the plasma levels remain constant because the rate of drug delivered from the patch is constant. When an oral drug is given two to four times a day, as is the case with most oral opioids, the drug level rises after administration and then gradually falls until the next administration, producing peaks and troughs throughout the course of therapy.
- Transdermal drug delivery systems, especially simple patches, are easy to use and noninvasive and patients like noninvasive therapies.



 Because they are easy to use, patches can increase compliance and reduce medical costs. There are many studies that show a patient's overall healthcare costs are reduced when pharmaceutical compliance is increased. In addition, there are specific studies that show that patient compliance increases and healthcare costs decrease when patches are prescribed.

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.

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, most of the times, medications whose active ingredients 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 (see the following table).



Partial list of Currently Approved TTDS

Year	Generic (Brand) Names	Indication
1990	Fentanyl (Duragesic)	Chronic Pain
1991	Nicotine (Nicoderm, Habitrol, Prostep)	Smoking cessation
1993	Testoterone (Androderm)	Testosterone deficiency
1995	Lidocaine/epinephrine (Lontocaine)	Local dermal analgesia
1999	Lidocaine (Lidoderm)	Post herpetic neuralgia pain
2004	Lidocaine/ultrasound (SonoPrep)	Local dermal anesthesia
2005	Lidocaine/tetracaine (Synera)	Local dermal analgesia
2006	Fentanyl/iontophoresis (Ionys)	Acute postoperative pain
2007	Rotigotine (Neupro)	Parkinson's disease
2010	Buprenorphine (Butrans)	Chronic pain

The transdermal delivery of opioids provides some advantages. It avoids the peaks and troughs of intermittent dosage regimens that can lead to side-effects such as sedation, nausea and vomiting, and respiratory depression. The reduced need for dosage administration (72 hourly or weekly) also improves patient compliance.

Opioid TDDS have proven to be efficacious in the long-term management of chronic malignant and non-malignant pain. Transdermal opioids have found applications in managing patients suffering with chronic low back pain and chronic musculoskeletal disorders. In both groups, patient satisfaction is greater with preference for transdermal drug delivery as this is associated with less side-effects (e.g. constipation) and is more convenient. Improvements in measures of quality of life have also been reported in cancer pain patients receiving opioid TDDS.



Opioids for Chronic Pain: Vast Growing Market

Pain is a disabling symptom that can occur at any point in the course of many illnesses and injuries, and even following some medical procedures. Since pain considerably affects day to day life, its management offers considerable challenges for physicians, patients, and society in general. Inadequate pain control remains a major problem across the world. Pain relief medications, also known as analgesics, are dominated by commonly used nonsteroidal anti-inflammatory drugs (NSAIDs), simple analgesics like paracetamol/acetaminophen, and opioids. Long acting, or extended release, opioids are used in the relief of moderate to severe chronic pain, which requires treatment in some cases for months or even years. Opioids are prescribed when pain cannot be adequately controlled with an NSAID or other simple analgesic.

At higher doses, which may often be needed for moderate to severe pain, NSAIDs/COX-2 inhibitors can have cardiovascular and renal side-effects, and the older NSAIDs also have severe gastrointestinal effects like nausea and ulceration. Therefore, in cases of acute and chronic pain, opioids continue to be a mainstay of therapy. In 2013, the global opioid 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.





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, fentanyl, and oxycodone (OxyContin) work by blocking pain signals to the brain. 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-opioid medication is ineffective, or in conjunction with other painkillers. The most common conditions treated with opioid pain medications include cancer pain, low 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 the US 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, 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.

Animal Health: Reducing Use of Antibiotics

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One of the outcomes of this year's 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 TPMcontaining animal feeds and supplements are already available in several countries. Phosphagenics is actively working on a series of trials to provide more compelling data to help facilitate future partnerships, and is looking for further distribution of TPM-containing products for the animal nutrition industry, for various food chain species.

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, nonantibiotic treatments could improve consumer and regulator confidence by reducing the overall usage of antibiotics in food chain animals.



Pipeline Phosphagenics Animal Health



Partnered 🛛 🚧 Not Partnered

Phosphagenics' R&D program in Animal Health includes up to eight trials, that almost all will offer significant milestones in the next 3-12 months.

Recently, Phosphagenics announced that a second swine study targeting meat quality and feed efficiency was initiated in December. This study follows-on from the first successfully completed weaner (young) pig study. In January the company announced positive results with the weaner pig study. Results showed that TPM outperformed standard Vitamin E as feed additive. The study compared the benefit of TPM® at doses of 5 to 40 mg/kg with that of increasing doses of Vitamin E (dl-alpha-tocopherol acetate) up to 160mg/kg across the first two development phases post weaning (phase 1: 0-14 days and phase 2: 15-34 days). Weaner pigs are subjected to significant metabolic stress due to high growth rates, change of diet and social stress which can result in significant production limitations, particularly during the first of these phases. It is believed that supporting pigs at this early stage of the commercial lifecycle provides the opportunity for maximum growth potential long-term, conferring a potentially significant financial benefit to farmers and the food industry. In the first phase (0-14 days), TPM® treatment resulted in a statistically significant, linear dose dependent improvement in feed efficiency. The FCR with



40mg/kg of TPM® was more than three percent (>3%) better than the best result achieved with any dose of Vitamin E. The potential for further improvement in FCR exists at higher doses of TPM® than used in the current study. The significant difference observed in the first phase of the trial was not seen in the second phase (days 15 – 34 of treatment). Unforeseen health issues in the pigs during this second phase resulted in significant suppression of performance across the board for all treatment groups, compromising FCR assessments.

The second study targets older pigs and will complete the initial Pig program. The outcomes of these studies have been designed to be both commercially relevant and provide the necessary information required for prospective commercial partners to assess the value of TPM[®] across the production lifespan of pigs The results for the grower/finisher pig study is expected in 2016Q2.



SWOT Analysis

Strengths

Strong management with extensive relevant technical, commercial and financial expertise

Strong IP position, with some patents active past 2030

Relatively low risk strategy primarily focusing on the reformulation of existing drugs

Weaknesses

Operating losses accumulating year-on-year

Delayed clinical trials with TPM, particularly the TPM/Oxymorphone patch

Opportunities

Key data for TPM/Oxycodone patch and for TPM as an animal feed additive expected soon

Additional products to leverage off the current platform technology and existing IP

Targeting new markets in animal nutrition and in pharmaceuticals

Threats

Delay in rollout of products in major markets

Failure to sign partnerships in key markets



Patent Position

Phosphagenics' patent portfolio comprises 14 patent families, with about 90 granted patents including 6 patents granted in the US, 5 in the EU and 33 patents granted by individual European jurisdictions. Additional patents are currently pending, and additional patent families are planned to be filed.

Patent Family	Official Title/Abstract	Status/Expiry
1.The carrier composition comprising TPM, ethanol and water, which may form vesicles PCT/AU2006/000839	Title: A carrier comprising one or more di and/or mono- (electron transfer agents) phosphate derivatives or complexes thereof. Abstract: The invention relates to a carrier for administering biological lyactive compounds comprising one or more C1- C4 alcohols, polyols and polymers thereof, water and one or more di and/or mono-(electron transfer agent) phosphate derivatives or complexes thereof. The carrier may be used in administering biologically active compounds, in particular pharmaceuticals including cosmetic agents.	Granted by Australia, Canada, China, Hong Kong, Japan, Mexico, New Zealand, Russia, Singapore, South Africa (pending in the United States) Anticipated expiry: 2026
2.TPM emulsion formulation PCT/AU2004/001475	Title: Formulation containing phosphate derivatives of electron transfer agents Abstract: There is provided an emulsion composition for therapeutic administration comprising: (a) at least one mono-electron transfer agent phosphate derivative; (b) at least one di-electron transfer agent phosphate derivative; wherein the amount of mono-electron transfer agent phosphate derivatives is no less than equimolar to the amount of di-electron transfer agent phosphate; and (c) a suitable carrier.	Granted in Australia, Canada, China, Denmark, European Patent Office, France, Germany Hong Kong,, Ireland, Italy Japan, Mexico, Netherlands, Korea, Spain, Switzerland, Turkey, UK, United States (two patents granted) Anticipated expiry: 2021
3.Dermal therapy (e.g. methods of treating a skin condition) PCT/AU2002/001003	Title: Dermal therapy using phosphate derivatives of electron transfer agents Abstract: There is provided a method for preventing, alleviating symptoms or treating a skin condition comprising topically administering to the skin of a subject a cosmetic or pharmaceutical topical formulation comprising an effective skin-penetrating amount of one or more phosphate derivatives of one or more electron transfer agents.	Granted in Australia, Canada, Japan, United States Anticipated expiry: 2021



Family	Official Title/Abstract	Status/Expiry
4.Complexes of phosphate derivatives PCT/AU2001/001476	Title: A carrier comprising one or more di and/or mono- (electron transfer agents) phosphate derivatives or complexes thereof. Abstract: There is provided a composition comprising the reaction product of: a) one or more phosphate derivatives of one more orehydroxylated actives; and b) one ore more complexing agents selected from the group consisting of amphoteric surfactants, cationic surfactants, amino acids having nitrogen functional groups and proteins in amino acids.	Granted in Australia, European Patent Office Anticipated expiry: 2021
5.A carrier (comprising TP) for enteral administration of biologically active compounds PCT/AU2005/001159	Title: A carrier for enteral administration. Abstract: There is provided a carrier for use in enteral administration of biologically active compounds, said carrier comprising an effective amount of one or more phosphate derivatives of one or more electron transfer agents.	Granted in Australia, Canada, China, European Patent Office, France, Germany, India, Japan, Mexico, New Zealand, Russia, Singapore, South Africa, UK, (pending in the United States) Anticipated expiry: 2025
6.An alkaloid formulation comprising a reaction product of an alkaloid and TP PCT/AU2005/000307	Title: Alkaloid formulations Abstract: There is provided an alkaloid formulation comprising the reaction product of one or more alkaloids with one or more phosphate derivatives of one or more electron transfer agents.	Granted in Australia, Canada, China, Denmark, European Patent Office, France, Germany, Hong Kong, India, Ireland, Italy, Japan, Mexico, Netherlands, New Zealand, Korea, Russia, Singapore, South Africa, Spain, Switzerland, Turkey, UK, United States Anticipated expiry: 2025
7.The phosphorylation process for producing TP PCT/AU2000/000452	Title: Improved Process for Phosphorylation and Compounds Produced by this Method Abstract: A process for phosphorylating primary fatty alcohols, secondary alcohols, or aromatic alcohols comprising the following steps: (a)forming an intimate mixture of one or more of the above alcohols and P4O10 or partly hydrated P4O10 or a mixture thereof at a temperature below 80 °C; and (b) allowing the intimate mixture to continue to react for a period of time at a temperature below 80 °C until the formation of the dihydrogen form of the phosphorylated alcohol is substantially formed.	Granted in Australia, Canada, European Patent Office, France, Germany, Japan, Mexico, UK, United States Anticipated expiry: 2020



Family	Official Title/Abstract	Status/Expiry
8.The the "high solvent" carrier composition PCT/AU2010/001719	Title: Carrier composition Abstract: A carrier composition of the present invention comprises a phosphate compound of an electron transfer agent and a relatively high concentration of a polar protic solvent. A biologically active compound may be formulated with a carrier composition of the present invention to provide a formulation.	Granted in Singapore, South Africa (pending in the United States) Anticipated expiry: 2030
9.The carrier comprising non- neutralised TP PCT/AU2011/000112	Title: The carrier comprising non-neutralised Tocopheryl Phosphate Abstract: The present invention relates to a carrier for the delivery of a nutraceutical or cosmeceutical active comprising non%- neutralised to copherylphosphate and a hydrophobic vehicle. The present invention also relates to a formulation comprising the carrier and a nutraceutical or cosmeceutical active.	Granted in Hong Kong, (pending in the United States) Anticipated expiry: 2031
10.The "alternate solvent" carrier composition PCT/AU2011/000122	Title: The "alternate solvent" carrier composition Abstract: The present invention relates to a carrier composition comprising a phosphate compound of an electron transfer agent and a polaraprotic solvent. Biologically active compounds formulated with the carrier composition have been shown to have improved properties.	Granted in Hong Kong, Singapore, South Africa (pending in the United States) Anticipated expiry: 2031
11.Trandermaldelivery patch (opioids) PCT/AU2010/000580	Title: The "alternate solvent" carrier composition Abstract: A composition suitable for use in a transdermal delivery patch for administration of an opioid, the composition comprising a phosphate compound of to copherol and a polymer carrier.	Pending only (pending in the United States) Anticipated expiry: 2030



Family	Official Title/Abstract	Status/Expiry
12.Transdermal delivery patch (general) PCT/AU2011/000358	Title: Transdermal delivery patch. Abstract: A composition suitable for use in a transdermal delivery patch for administration of a biologically active compound, the composition comprising a phosphate compound of to copherol and a polymer carrier.	Granted in Hong Kong, Singapore, South Africa, the United States Anticipated expiry: 2031
13.The composition for the treatment of mastitis PCT/AU2012/000220	Title: Formulation containing phosphate derivatives of electron transfer agents Abstract: Compositions and formulations comprising a non-neutralised to co-phosphate and a vitamin A compound, which are suitable for the treatment of inflammation and/or infection in breast or udder tissue, more particularly in a mammary gland, reducing the somatic cell count in a lactating subject and supplementing vitamin E levels in a subject.	Pending only (pending in the United States) Anticipated expiry: 2032
14.Formulation	Title: Formulation. Abstract: This patent has not yet been published, so we are not in a position to share any details at this stage.	Pending only (not yet submitted in the United States) Anticipated expiry: 2031



Financials

For the six months ended 30 June 2015, revenue from continuing operations was up 113% to AUD 1.0 million (2014H1: AUD 0.5 million) with strong first half sales from Vital ET. Total other income was AUD 1.5 million (2014: AUD 3.4 million), including AUD 0.1 million (2014: AUD 2.1 million) from the recovery of misappropriations and AUD 1.0 million (2014: AUD 1.1 million) relating to the R&D tax incentive. Expenses for the period include non-cash impairment losses of AUD 7.8 million (2014: nil) as a result of an independent valuation of the acquired patent portfolio. From 2005, under its accounting policy, the company has not capitalized the value of six patents developed from internal research and consequently no book value for these is shown within the Balance Sheet. Cash at 30 June 2015 totaled AUD 15.8 million (31 December 2015: AUD 20.7 million). Other receivables includes approximately AUD 5.0 million relating to the R&D Incentive rebate for 2014 and 2015 which will be received in the second half. Recently the company announced that it received its R&D Tax Incentive refund amounting to AUD 2.6 million for the 2013-14 tax year.

Based on orders from the Company's distributor, Ashland Inc, up to June 2015, total sales of Vital ET will exceed those for 2014 (AUD 1.5 million). Licensing of TPM to Le Métier de Beauté (LMDB), which was acquired by a private US investor in 2014, continues to provide modest royalty income for Phosphagenics.

In the first half of this year, Phosphagenics signed an agreement with Integrated Animal Health (IAH) to sell feedstock (Feed-Mate) which included TPM® for distribution in the UK and Ireland by distributor, Denis Brinicombe Group. The agreement specified minimums equating to 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.



Financial Summary (AUD million)

Profit & Loss Statement	June 30 2015A	June 30 2014A
Revenues	0.978	0.459
Cost of Sales	(0.315)	(0.132)
Income from government grants	0.989	1.069
R&D Costs	(1.040)	(0.933)
General & administrative expenses	(6.639)	(3.001)
Depreciation	(1.926)	(1.923)
Impairment losses	(7.837)	-
Income (loss) before income taxes	(13.405)	(2.118)
Loss from discontinued operations	(0.495)	(0.667)
Net Loss (Income)	(13.900)	(2.785)

Consolidated Statement of Cash Flows

	June 30th 2015A (6 months)	June30th 2014A (6 months)
Cash flow from operating activities	(4.825)	(1.170)
Cash flow from investing activities	(0.022)	(0.013)
Cash flow from financing activities	-	-
Cash and cash equivalents at beginning of the period	20.679	8.823
Net change in cash and cash equivalents	(4.847)	(1.183)



Valuation

We arrive at a value of AUD 100-115 million for Phosphagenics using a risk adjusted Net present value based on future income from TPM®/Oxycodone and TPM®/Oxymorphone patches. Income from Animal Health and Personal Care have not been taken into account and will offer additional upside potential. Our forecast includes sales of TPM®/Oxymorphone Patch and TPM/Oxycodone Patch reaching revenues by 2031 of USD 75 million and USD 500 million respectively. We estimate that the TPM®/Oxymorphone Patch can reach a market share of 5% whereas we expect that the TPM®/Oxycodone Patch can reach a peak market share of 15%. Phosphagenics will sell the patches via partnerships. For TPM®/Oxycodone we believe that tiered royalties are expected of 16-20%. For TPM®/Oxymorphone we expect royalties of 16%.

Year	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
Price per dosage (monthly)	400	412	424	437	450	464	478	492	507	522	538	554
Number of dosages (mln yearly)	60.00	61.50	63.04	64.61	66.23	67.88	69.58	71.32	73.10	74.93	76.81	78.73
Market share TPM/Oxycodone	0.2%	0.4%	1.0%	1.5%	2.5%	4.0%	6.0%	8.5%	10.0%	11.5%	13.5%	15.0%
Market Oxycodone (mln)	2400	2472	2546	2622	2701	2782	2865	2951	3040	3131	3225	3322
Net Rev TPM/Oxycodone	4.8	9.9	25.5	39.3	67.5	111.3	171.9	250.9	304.0	360.1	435.4	498.3
Royalty 16%-18%-20%	0.77	1.58	4.07	6.29	10.80	17.81	28.95	44.18	54.80	66.02	81.09	93.66
WACC 11%	0.73	0.66	0.59	0.53	0.48	0.43	0.39	0.35	0.32	0.29	0.26	0.23
NPV (million)	0.56	1.04	2.42	3.37	5.20	7.73	11.32	15.56	17.39	18.87	20.88	21.73
Total NPV (million)											1	104.3
Chance of success 50%												
Risk adjusted NPV (USD)											ţ	52.2
Value per share (AUD)											(0.06

Sales forecast and valuation TPM®/Oxycodone (USD)



Sales forecast and valuation TPM®/Oxymorphone (USD)

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Year	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
Price per dosage (monthly)	400.0	412.0	424.4	437.1	450.2	463.7	477.6	491.9	506.7	521.9	537.6	553.7
Number of dosages (mln yearly)	26.0	26.5	27.1	27.6	28.2	28.7	29.3	29.9	30.5	31.1	31.7	32.3
Opioid Market (mln USD)	10404	10930	11484	12065	12675	13316	13990	14698	15442	16223	17044	17907
Market share TPM/Oxymorphone patch	0.1%	0.4%	0.8%	1.2%	2.0%	2.6%	3.4%	4.0%	4.5%	5.0%	5.0%	5.0%
Net Rev TPM/Oxymorphone	0.87	3.64	7.66	12.06	21.13	28.85	39.64	48.99	57.91	67.60	71.02	74.61
Royalty 16%	0.13872	0.58	1.22	1.93	3.38	4.62	6.34	7.84	9.27	10.82	11.36	11.94
WACC 11%	0.73	0.66	0.59	0.53	0.48	0.43	0.39	0.35	0.32	0.29	0.26	0.23
NPV (million)	0.10	0.38	0.73	1.03	1.63	2.00	2.48	2.76	2.94	3.09	2.93	2.77
Total NPV (million)											:	22.8
Chance of success 60%												
Risk adjusted NPV (USD)												13.7
Value per share (AUD)												0.016

We estimate the US markets to be 70% of all opioids markets. We derive from this that the European market will be 20% of the total opioid market. That leads to an additional valuation for Phosphagenics of USD 10.4 million and USD 2.7 million additionally or AUD 0.011 and AUD 0.002 per share additionally.

In our valuation model for Phosphagenics, we do not include revenues from Animal Health and Personal Care as well as potential revenues outside of the US & EU. Additional revenues from these divisions offer additional upside potential. **Applying a WACC of 11%, we value Phosphagenics at AUD 0.09 per share (based on a USD/AUD exchange rate of 1.44).**

Management Capabilities

Seasoned innovators in healthcare, animal care and manufacturing are rebuilding Phosphagenics. The company is led by an experienced and renewed board and management team, which has been responsible for the new strategy of the business and has a successful track record of developing, protecting and commercializing innovative scientific products and processes. In the past several years, Phosphagenics has been investing in developing a team of experts that have a focus on patient outcomes and can deliver results. Its board and senior management team are highly experienced in the development and commercialization of newly defined therapeutics in pain management and dermatology / skin care. In the first six months of 2015, the company underwent a major transition with the appointment in January 2015 of Dr Ross Murdoch as CEO followed in April by the appointment of new directors Mr Peter Lankau and Dr Greg Collier.

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Management Team

Ross Murdoch, Chief Executive Officer

Dr Murdoch joined Phosphagenics as CEO in January 2015. He has more than 25 years' experience as a leader within the global Healthcare, Pharmaceutical and Biotechnology Industry. He has held senior management and executive positions in Australia, USA and Europe, with responsibility for the strategy, development and commercialisation of products, product portfolios and the building and rebuilding of new and existing businesses. Highlights of his career include Senior Vice President at Shire Pharmaceuticals (one of the world's leading Specialty Pharmaceutical companies), based in the USA and Switzerland, where he founded and grew both the Emerging Products Business and Haematology Business, and President and COO of Prana Biotechnology Limited based in Australia. Dr Murdoch has a BSc degree with honours from Monash University, a PhD in Clinical Pharmacology from the University of Melbourne, and additional postgraduate training in Health Economics from Monash University Business School.



Paul Gavin, Chief Scientific Officer

Dr Gavin is responsible for the global coordination and management of the company's preclinical and clinical research. Since joining Phosphagenics in 2002, he has developed multiple opportunities for the Company such as transdermal drug delivery systems and drug enhancement platforms for chronic pain management. Dr Gavin is an inventor of the TPM® platform technology for transdermal delivery, and has managed its evolution from discovery to clinical development, with a range of products. Dr Gavin holds a BSc (Honours) and PhD in Biochemistry & Molecular Biology from Monash University, Melbourne. He is experienced in many aspects of R&D and has published a number of articles in peer reviewed journals.

Anna Legg, Chief Financial Officer

Ms Legg joined Phosphagenics in January 2013. She has over 15 years of experience in financial management in government, as well as private and public companies. She has been involved in establishing international entities covering their tax, legal and funding requirements. Her particular strengths include statutory reporting, system development and financial modelling. Ms Legg works closely with the CEO and Senior Management Team to provide financial support for the growth of the business in Australia and internationally. Ms Legg holds a Bachelor of Economics from Macquarie University, Sydney and a Diploma in Law from the Legal Profession Admission Board, Sydney.

Alex Stojanovic, VP Business Development & Commercial Operations

Dr Stojanovic joined Phosphagenics in early 2014. He has spent 7 years as a strategy consultant, during which time he has advised more than 30 life science companies on various aspects of business development, corporate strategy, marketing, and market access. Dr Stojanovic also served as Senior Director of Global New Compound Marketing at Grunenthal GmbH, managing the global commercial development of two pipeline pain molecules, and brings a wealth of



experience in commercializing opioids. He received a PhD in Pharmacology & Toxicology from Dartmouth College, and BS degrees in Chemistry and Cell & Structural Biology from the University of Illinois.

Roksan Libinaki, GM Animal Health and Nutrition

Dr Libinaki is responsible for the global coordination and management of the company's Animal Health and Nutrition, Research & Development programs. Since joining Phosphagenics in 2001, she has been involved and managed numerous, pre-clinical and clinical development programs with a focus on oral drug delivery systems and drug enhancement platforms to improve bioavailability and/or efficacy of a range of nutrients, and drug activities, for the purpose of improving health and well-being for both humans and animals. Dr Libinaki holds a Bachelor of Science (Biomedical) (Hons) and a PhD in Biochemistry and Molecular Biology from Monash University in Melbourne. She has collaborated and overseen numerous academic and commercial research programs and has extensively published in peer reviewed journals.

Greg Moses, GM Operations and Production

Mr Moses joined Phosphagenics in November 2012 as GM Personal Care, and has been in his current role since April 2015. His experience spans wholesale and retail brand development. He was previously 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. Mr Moses also spent several years as a Business Manager for Myer Grace Bros and was part of the team responsible for returning the failing Bendigo store into a profitable operation. At Phosphagenics, Mr Moses has been managing both the branded products under the BioElixia® label and the bulk formulation products sold to companies like GNC.



Expected News Flow

Over the next 3-12 months, the company is expecting considerable news flow from each of its divisions Human Healthcare, Animal Healthcare and Production/Personal Care. Each of these news items can have a potential effect on the share price.

Human Healthcare

- > Reformulation of TPM[®]/Oxymorphone patch: 2016Q2/2016Q3
- > Key development milestone for its injectable antibiotic from Mylan: 2016H1
- Regulatory meeting with FDA on key development issues for both opioid patches: 2016H1

Animal Healthcare

- > First results for Swine LWG program: 2016Q1
- First results for Poultry LWG program: 2016H2
- > Cattle trials Somatic cell count/Fertility program: initiates: 2016H1

Production/Personal Care

- > Increase TPM[®] manufacturing capacity (complete upscale reactor plant):2016H1
- > Promising personal care relationships being negotiated: 2015H2/2016H1



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.

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