



PHOSPHAGENICS

*ASX Limited  
Market Announcements Office*

## **Annual General Meeting 2014**

**23 May 2014, Melbourne, Australia**

**Attached for release to the market is a copy of each of the following presentations to be given at today's Annual General Meeting of Phosphagenics Limited:**

**Chairman's Address by Mr L Gozlan;**

**Chief Executive Officer's Address by Mr H Rosen; &**

**Chief Scientific Officer's Presentation by Dr P Gavin**

### **About Phosphagenics**

Phosphagenics Limited is commercialising drug delivery applications based on its novel transdermal (drugs administered via skin) TPM<sup>®</sup>. Targeted Penetration Matrix technology. TPM<sup>®</sup> is a patient friendly and cost effective system used to deliver proven pharmaceutical and nutraceutical products.

The lead products advancing through clinical trials are an oxymorphone and oxycodone matrix system for the relief of chronic pain. These products are part of a pain portfolio of currently five main products including a diclofenac patch and gel and a lidocaine patch.

Phosphagenicsq technology also has application in a diverse number of areas including animal health, bulk and branded cosmetic formulations and dermatological product solutions.

Phosphagenicsq shares are listed on the Australian Securities Exchange (ASX: POH) and its ADR . Level 1 program in the US is with The Bank of New York Mellon (OTCQX: PPGNY).

[www.phosphagenics.com](http://www.phosphagenics.com)  
[www.bioelixia.com](http://www.bioelixia.com)

## ASX Limited Market Announcements Office

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### Annual General Meeting (“AGM”), Melbourne 23 May 2014

#### Chairman’s Address – Mr Lawrence Gozlan

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Good afternoon and on behalf of the Board, our senior management team and all of our valued staff, I would like to welcome you to the annual general meeting of Phosphagenics. Unfortunately one of our directors, Geert Cauwenbergh, could not be here today. To make time for this appointment, he has had to unwind other commitments over the last 3 months to ensure a smooth handover and it was not possible for him to match dates with these prior commitments.

Phosphagenics has had a tumultuous period last year, of which the CEO will address in his speech. As a new board was appointed in March 2014, I will focus on the bright future going forward, not the past.

Principally, I joined the Board because of the compelling technology. I have been familiar with the company for many years and have seen it evolve from producing vitamin E phosphate as an active into a transdermal platform delivery system with a suite of pain relief products addressing large markets. Phosphagenics strategy to focus on opioids has proven very valuable. In October 2013, the management team announced the results of the Phase 1 multi-dose oxymorphone study which exceeded our most optimistic expectations. We were able to show that our patch delivered oxymorphone through the skin and into the bloodstream at concentrations equivalent to the oral oxymorphone product Opana®ER. The plasma concentrations of each patient were above therapeutic levels and, consequently, we are confident we have a patch that is therapeutic. There are still hurdles in front of us, but to my knowledge this is something that has never been done before in the pharmaceutical industry, which represents an enormous opportunity for the company and shareholders.

While generally not understood, a biotechnology company developing a drug delivery platform is significantly different to biotechnology companies developing new drugs. Drug delivery companies create new ways of more effectively administering existing drugs whose efficacy is well known and proven. This clearly has a different risk profile to a company that has to establish efficacy, instead we need to show we can deliver a drug to achieve a therapeutic dose. Establishing efficacy for new drugs typically commences during a Phase 2 study. Therefore, it should be understood that our successful multi-dose oxymorphone study can be compared to a successful Phase 2 in terms of de-risking the program.

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### Phosphagenics Limited

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Opioids are a first line medication for chronic pain. However, they do cause many side effects including respiratory depression, constipation, vomiting and drowsiness, as well as abuse and tolerance issues. The administration of opioids transdermally should reduce many of these side effects as well as more effectively relieve pain. This should lead to better patient safety and better therapy.

The Company is tackling the extended release chronic pain market with our oxymorphone patch and the peripheral pain market with our oxycodone patch. Each of these markets is large with the sales of opioids in the extended release chronic pain market exceeding US\$5 billion per annum in the US and the peripheral pain market exceeding US\$6 billion per annum globally.

My fellow Directors and I see great potential for the Company to become a leading Australian biotechnology company. While our primary focus remains on pain, TPM<sup>®</sup> is a technology with wide applications into many fields such as dermatology and animal health. The successful commercialisation of the pain portfolio will not be the end of the growth of this Company but merely the beginning of our compelling future.

Our Directors are veterans in the biotechnology industry, two of which are US based. As we continue with our development, more of our focus will turn to the US as it is the global centre of pharmaceutical industries and markets. We have a strong management team with qualified executives joining our Company over the past few months. I am confident we have the right elements in place for success.

While our focus is on executing our strategic vision, on behalf of the Board I can also assure our shareholders that the Board will ensure that we have the highest standard of corporate governance and financial control systems in place to avoid any future issues related to financial impropriety.

I'd like to take this opportunity to again thank the many talented people at Phosphagenics who have driven the enormous progress - all of the company's employees and executive management, led by CEO Harry Rosen and CSO Dr Paul Gavin, and my fellow board members.

Finally, to our shareholders. Thank you for your continued support in our company. We have many loyal shareholders which is testament to the very significant opportunities for our multiple products to improve patients' lives. Whether it is improving the management of pain, both chronic and peripheral, control of acne, or enhancing animal health, we have an enormous opportunity that carries significant commercial value.

**END**



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## **Annual General Meeting 2014 CEO Address**

**23 May 2014, Melbourne, Australia**

At Phosphagenics we have worked through the legacy left by our former CEO and have moved on. Despite this event we continue to hit key milestones. Our world-class oxymorphone results in October and the agreement with Novartis India justifies the focus on our pain portfolio, with its particular emphasis on opioid patches.

Having a great technology does not guarantee success. Combining a great technology with a talented and dedicated group of people greatly improves the odds. We have both these elements.

To our staff, most of whom are here today, I want to publicly thank you for your devotion to our company which has surpassed even my high expectations. I am blown away by your determination not to allow the events of 2013 to dampen your enthusiasm. Your passion for success is unsurpassable. To those who have recently joined us, your expertise and support is greatly welcomed. Added to my personal gratitude, I also thank you on behalf of our shareholders.

While I do not want to dwell on Eragate as we refer to it, I appreciate that many of you want answers. As such, I will devote some time addressing this. However, before doing so I want to emphasize that I am restricted in what I can say by legal considerations. We are bound by confidentiality provisions under the various Deeds of Settlement we have signed. For obvious reasons I cannot even publicly hint at what our ongoing strategies are to maximise the recovery of funds. Lastly we do not want anything I say today to impact adversely on Phosphagenics or leave it open, even remotely, to the possibility of future litigation.

Ogru's alleged actions were such an overwhelming breach of trust, a breach of fiduciary duty that I find it almost impossible to put into words the extent of her infidelity to our staff and shareholders. Its negative impact on our reputation at every level, corporately and individually, was swift and brutal. Its effect on our share price lingers and even today undermines and frustrates our efforts to ascribe our company with a fair market value. In all the years I have spent in public companies I have resisted the temptation of saying anything about share-price. Today I will tell you that based on our current development, ours is greatly undervalued. I am confident that this will change as we continue to work towards re-building our credibility and hitting our milestones.

While some have questioned our technology, let me be very clear and leave you in no doubt whatsoever when I say that the integrity of our technology and the commercial strategy we have in place, remains unimpeachable.

While nothing prepares you for the magnitude of Ogru's alleged betrayal, the action taken by our former board and management was instant and appropriate. As soon as the anomaly in our accounts became apparent we immediately suspended Ogru as CEO and placed our shares in a trading halt. The following working day we announced the fraudulent misappropriation to the market.

Our recovery efforts were also immediate and aggressive. We appointed forensic accountants who established that the amount allegedly misappropriated by Ogru and her fellow conspirators was \$6.3 million. Subsequently we reached agreement with two of the parties and their families. We issued legal proceedings against Gianello, a former employee, and his wife in the Supreme Court and consequently entered judgment against them. So far we have recovered approximately \$3.8 million of which \$2.6 million has come from Ogru and her immediate family. Gianello and his wife have declared themselves bankrupt and the trustee acting for their estate is in the process of liquidating their assets. We cannot estimate how much more will be recovered but it is likely to be another \$1 million or so. Currently we have just over \$9 million in the bank.

The alleged fraud should never have happened. It did. We cannot undo the past but we can and have learned from it. As I said earlier, the company has now moved on and is focused on commercialising our great platform technology. The investment community should do likewise. They should value our company on the merits of our technology and our commercialisation strategies rather than on the alleged criminal actions of a few misguided individuals.

Despite our trials and tribulations in 2013, it was a year of substantial progress. We developed and then optimised an oxymorphone patch to supplement oxycodone and expand our opioid portfolio. We undertook extensive marketing and physician surveys that enabled us to formulate a robust commercial strategy that sees our oxymorphone patch earmarked for chronic systemic pain and our oxycodone patch for peripheral pain.

The combined global markets for these products and indications exceed US\$12 billion annually. Their risk profile is very different. The oxycodone patch is designed to deliver its payload into the skin and consequently should have a relatively simple regulatory pathway. However, we need to demonstrate efficacy. On the other hand, oxymorphone is designed for systemic delivery, and based on our multi-dose study, efficacy is not problematic. Overarching this, the two patches will not compete in the same market.

Our development over the past 12 months has necessitated changes in the skillset required within our workforce. We have strengthened our US base by adding two business development people. More will follow. The US, which consumes 70% of the world's opioids, is crucial to our commercial success. In Australia we have changed the mix of people consistent with our transition. Four people left. We replaced them with an additional clinical development manager, a regulatory affairs manager, an experienced project manager and a quality assurance manager.

We engaged several leading US firms to advise us in the key areas of abuse and reimbursement. Initial review has not provided us with any concerns whatsoever. We remain confident about success. We have also collaborated with US regulatory advisors to compile the data required for a US IND for our oxymorphone patch. We expect to engage with the US FDA towards the end of this year in advance of a Phase 2 oxymorphone study in the US.

During the reporting period we commenced three clinical trials, being a single dose oxymorphone Phase 1 study, a multi-dose oxymorphone Phase 1 study and a tretinoin Phase 2 study for the reduction of acne. In October we announced the results of our Phase 1 multi-dose oxymorphone clinical trial. In a world first we were able to deliver

oxymorphone at therapeutic levels to all 12 subjects. These results were a great tonic to us all. We have been developing opioids for a very long time with many cynics believing that therapeutic delivery through a patch was impossible. While we recognise that we still have much work in front of us, we have overcome our biggest hurdle to success, the transdermal delivery of oxymorphone.

I would like to request your indulgence as I reflect on the rationale for our past strategies and my personal vision for the company's future.

The road to successful commercialisation of a drug is strewn with failure. A catastrophic failure for a biotechnology company is only one or two clinical studies away. On the other hand, success takes a series of clinical studies and much more. We choose to work in this industry mainly because success leads to incredible shareholder wealth and impacts on the quality of life for so many people. Most of us in the industry are driven by the latter; investors by the former.

The outcome for most biotechnology companies is usually binary. A drug succeeds or fails. At Phosphagenics we made the decision that the risks inherent in this strategy were unacceptable. Consequently we chose to develop several products with varying degrees of difficulty from relatively simple programs to complicated ones such as pain and opioids. Logically, the degree of difficulty usually correlates to the magnitude of the financial rewards.

Sales in the global pain market are a staggering \$40 billion annually. We have successfully formulated NSAIDs, lidocaine and opioids, which account for \$29 billion of this market. Although pain has been around forever, there remain large unmet needs that will be addressed by our technology, especially for periphery pain. Our focus is on our pain portfolio and within it the opioids because we are the only company to have transdermally delivered oxymorphone and oxycodone. We know that some of the large companies have tried and failed.

Licensing is the normal commercialising route for Australian biotechnology companies. Licensors pay milestone payments and royalties on sales, the quantum of which depend on projected sales and perceived risks to regulatory approvals. De-risking a project leads to greater milestones and royalty payments. We are in discussions with several pharmaceutical companies and not only for our opioid or other pain products. At the appropriate time we will assess whether to license early or hold until we further progress our programs. In the meantime we continue with product development.

I have been involved in the development of several successful technologies over the past 35 years. Phosphagenics' technology is by far the best I have been involved in or seen during that time. Armed with this technology and its diverse applications, with the right management and board, Phosphagenics is poised to become a substantial global company. To achieve this it must expand beyond the borders of Australia. Once financially independent, Phosphagenics should become an integrated company by producing and marketing its products. To get TPM® on the global stage it should divest some of its diverse assets.

Our former board members are highly experienced well-credentialed business people. Their integrity and honesty is beyond reproach. Since July 2013 I have been asked on many occasions why the board was not stepping down; why I was not stepping down as CEO. I have been abused and maligned predominantly by people who have no corporate experience, no idea what was required at the time and who are just ignorant.

On 1 July 2013 what Phosphagenics needed, what our staff demanded, was solidarity and stability, not change. Those calling for immediate change were simply reactionary. It would have been easy for our board to step down but they stayed on for no reason other than that it was in the best interests of the company. They stepped down in

February because that was the right time. I thank them for their actions, for their integrity and their counsel during difficult times.

I have been a founder of several listed companies. I never accepted the title of CEO. It has been well over 15 years since I thought of the idea of exploiting the shortage of natural vitamin E and turned to the most prolific inventor I have met, Simon West. TPM was conceived. With the help of others we took control of a listed company in 1999.

In the first few years we had no CEO, such was my aversion to the title and to the role. In 2005 the title was thrust upon me. I became joint CEO in 2009 with Ogru in name only. For the past few years my business card showed the title of President and Founder. Since I left legal practice in 1985 my only professional passion has been to develop and commercialise research. I assumed the role of CEO in July 2013 because it was in the best interests of the company.

Our company has all the right elements in place for success. It has a dedicated and loyal workforce. Its technology has been established. We have a dynamic business development team in place in the US. Our new board has had the time to become familiar with our company both commercially and technically. Irrespective of what outsiders may have said, I now feel comfortable stepping down as interim CEO and assume my passion of corporate and business development. While I have no plans to retire, at my stage of life it is fair to say that any role I assume is interim. We will vigorously look for a new CEO either in Australia or overseas.

We have a very good board in place. In Lawrence we have a very successful biotechnology fund manager, in Nathan a great investment banker and in Geert an experienced highly credentialed pharmaceutical executive who understands the issues facing fast-growing biotechnology companies. The addition of a few more experienced pharmaceutical executives will complete this board and make it exceptional.

### **Harry Rosen**

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### **About Phosphagenics**

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# Phosphagenics Limited

Annual General Meeting

*May 2014*

[www.phosphagenics.com](http://www.phosphagenics.com)  
(ASX: POH; OTCQX: PPGNY)





## Safe Harbour Statement

*This presentation, and any representations made before, during or after the presentation, may include forward-looking statements that are inherently subject to risks and uncertainties. These statements relate to, but are not limited to: (1) the safety or efficacy of, or potential applications for, Phosphagenics' TPM<sup>®</sup> platform technology; (2) the strength of Phosphagenics' intellectual property; (3) the timelines for Phosphagenics' clinical trials and regulatory processes for its different products; (4) the scalability and efficiency of manufacturing processes; (5) revenue projections, market share expectations, share price expectations and capital requirements.*

*Actual results may differ from the expectations expressed in these forward-looking statements, and the differences may be material (whether positive or negative). The risks that may cause Phosphagenics' actual results, performance or achievements to be materially different from those expressed or implied by such forward-looking statements, include but are not limited to: (1) risks inherent in the development, approval and commercialization of potential products; (2) uncertainty of clinical trial results or regulatory approvals or clearances; (3) changes to market trends or government laws or regulations; (4) the potential need for future capital; (5) dependence upon collaborators; and (6) protection of intellectual property rights, among others. Accordingly, you should not place undue reliance on these forward-looking statements.*





Phosphagenics Investor Presentation

# 1. COMPANY PIPELINE

# TPM<sup>®</sup> Pharmaceutical Pipeline

Product	Formulation	Therapeutic Area	Partner (Geography)	Preclinical	Phase I/II	Phase III	Marketed
Oxymorphone	Patch	Pain (opioid)	TBD	Not Partnered			
Oxycodone	Patch	Pain (opioid)	TBD	Not Partnered			
Tretinoin	Gel	Dermatology	TBD	Not Partnered			
Lidocaine	Gel	Pain (anesthetic)	TBD	Not Partnered			
Diclofenac	Patch	Pain (NSAID)	TBD	Not Partnered			
Lidocaine	Patch	Pain (anesthetic)	TBD	Not Partnered			
Ketoconazole	Gel	Dermatology	TBD	Not Partnered			
Propofol	Injectable	Anesthetic	TBD	Not Partnered			
Diclofenac	Gel	Pain (NSAID)	Novartis; Themis (India)	Partnered			
Antibiotic*	Injectable	Antibiotic	Mylan (Global)	Partnered			

There are several other projects in early research and development across various therapeutic areas

-  Partnered
-  Not Partnered



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\* This molecule cannot be disclosed for confidentiality reasons; this product has been licensed but not yet launched by Mylan

## RESEARCH ACHIEVEMENTS 2013

- TPM<sup>®</sup>/Oxymorphone patch delivers therapeutic amounts of oxymorphone transdermally suitable for the treatment of chronic pain – a world first
- TPM<sup>®</sup>/Oxycodone completes Phase I testing – looks appropriate for new indication
- TPM<sup>®</sup>/Tretinoin Gel enters Phase II clinical trial for acne
- Patent granted in the US for TPM<sup>®</sup>/Oxymorphone and TPM<sup>®</sup>/Oxymorphone patches – patent life until 2030
- External gap analysis of company's entire clinical, non-clinical, CMC and regulatory plans for oxymorphone product registration – passed with flying colours
- TPM<sup>®</sup> supplementation in dairy cows reduced somatic cell counts and anti-biotic use on farm (MMA)



## COMMERCIAL ACHIEVEMENTS 2013

- Novartis launched the first pharmaceutical product containing TPM® - Voveran TPM® (in India)
- Mylan licensed an injectable antibiotic containing TPM® for launch in the United States in 2015/16
- GNC launched the Total Lean, Toning Cream
- Seven racehorse supplements (EEA) & seven horse feeds (ENA) on market
- Five dairy cattle supplements (MMA) launched on market
- New BioElixia® Body Essentials and Stretch Mark Diminishing Crème launched throughout Australia and the US
- Revenue from Phosphagenics' cosmetics products and animal health products, that are already on market, is expected to grow in the second half of 2014



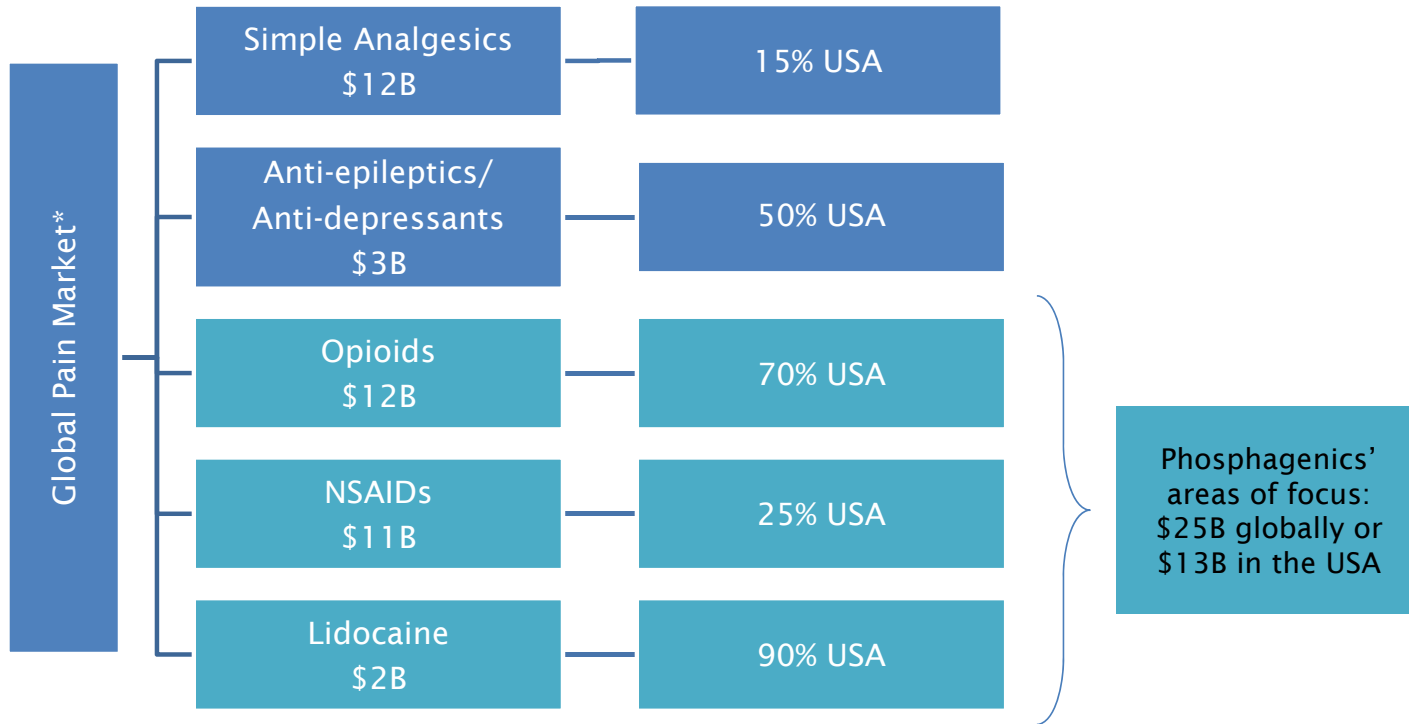


Phosphagenics Investor Presentation

## 2. COMMERCIAL OPPORTUNITY – PAIN ASSETS

# Global Pain Market

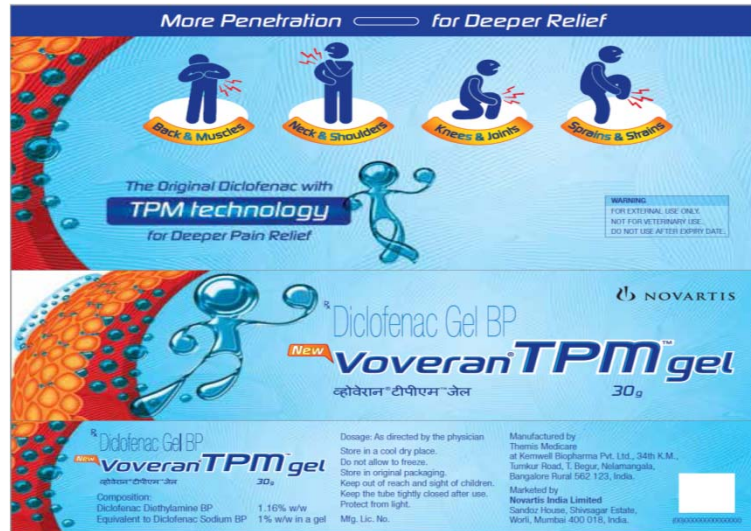
Pain therapeutics are worth about \$40 billion worldwide



\* Source: IMS World Review, 2011; Global Pain Market includes N2A ATC Class (Opioids), N2B ATC Class (Other Analgesics, chiefly paracetamol & acetylsalicylic acid), M1A ATC Class (NSAIDs), N3 ATC Class (Antiepileptics), N6 ATC Class (Antidepressants) and Lidocaine.

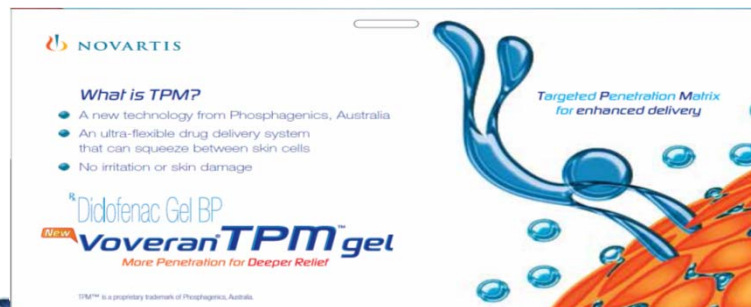
# NSAID Opportunity

## TPM®/Diclofenac Gel Novartis Packaging



Novartis recently launched the first pharmaceutical product containing TPM®. The product, called Voveran® TPM Gel, relies heavily on TPM® in its marketing. Novartis launched the product in India in January, 2014

Voveran® TPM® packaging (Front)



Voveran® TPM® packaging (Back)

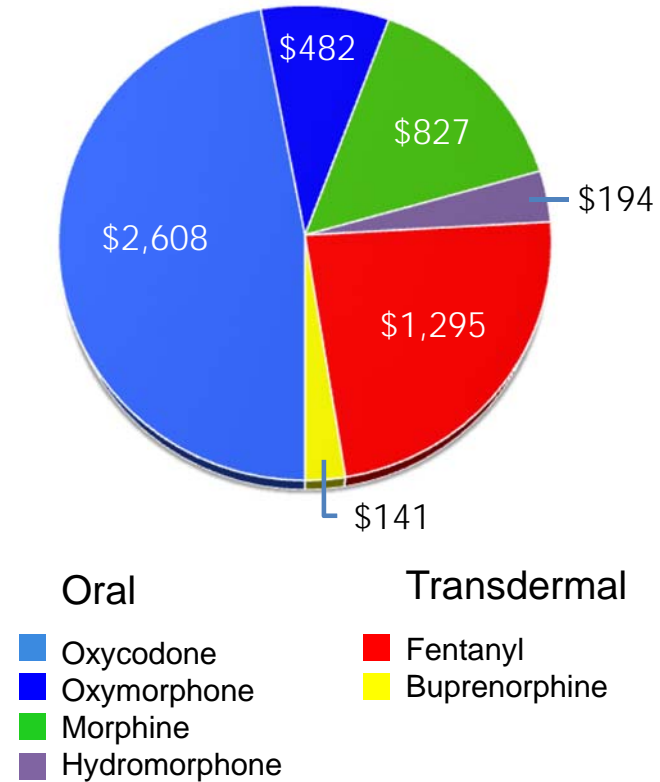


## Extended Release Opioid Market (USA)

US\$8 billion Opioid Market

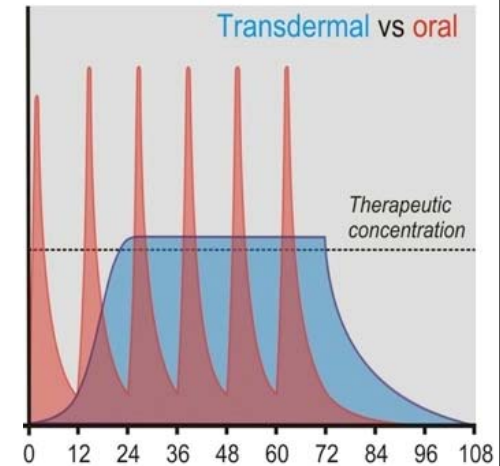
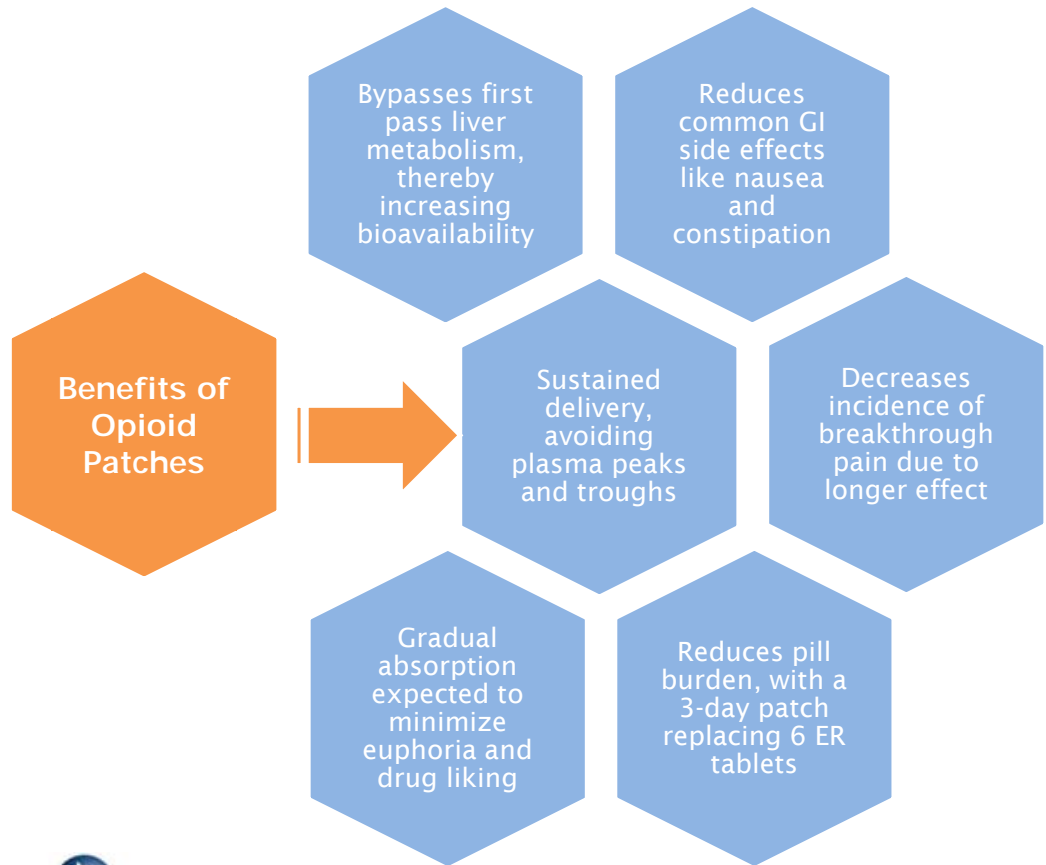
- ✓ Extended Release (ER) opioids account for 70% of the market by revenue (\$6 billion)
- ✓ Oxycodone and oxymorphone account for 50% of all ER opioid revenues (\$3B)
- ✓ Transdermal opioids (buprenorphine and fentanyl) account for 25% of all ER opioid revenues (\$1.5B)

Opioid Sales 2013  
(US\$ millions)



# Transdermal Opioid Opportunity

Opioid Patches have Many Advantages Over Oral Opioids



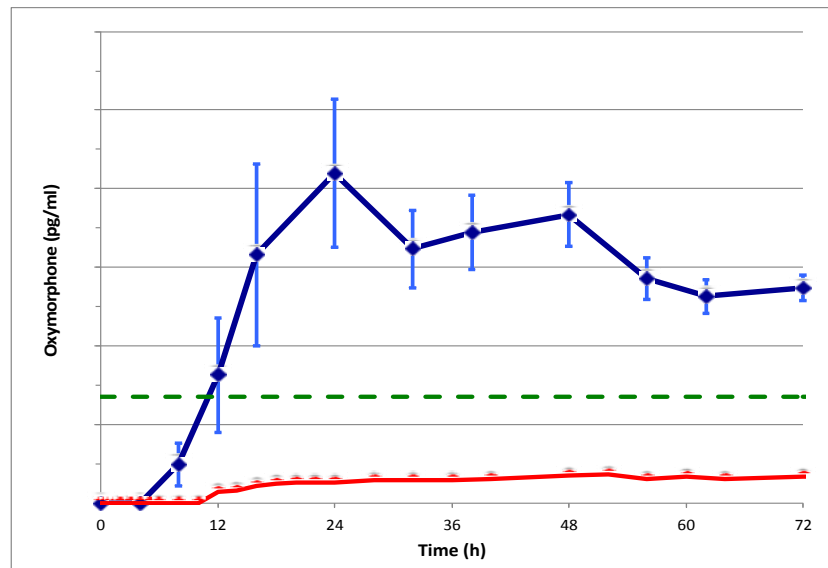
# Clinical Results

## TPM®/Oxymorphone Patch Phase 1 Data

### Single Application (72-hours)

- TPM®/oxymorphone delivers for the full 72-hours of application
- All subjects (n=12) in therapeutic plasma range\*
- Individual CMAX values as high as 2.2ng/ml from a single patch application

Mean plasma oxymorphone concentration, n=12, bars = SEM



The amount of oxymorphone used in the patch was up to 75% less than the amount that would have been used for pain administration using tablets over the same 72 hour period

- TPM®/oxymorphone patch
- First prototype oxymorphone patch
- - - Therapeutic plasma concentration\*

\*Single dose CMAX of the lower strengths of oral Opana ER®. All values higher than this are considered therapeutic.

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Phosphagenics Investor Presentation

## 3. LICENSING AND DEVELOPMENT

## FDA registration

Studies required for FDA registration of TPM®/Oxymorphone

- *Human clinical studies*
  - A series of studies used to define aspects of product labelling (ie. Pharmacokinetics, different application sites)
  - Two well controlled efficacy studies (Phase II or III)
- *Non-clinical toxicology*
  - Dermal toxicity
  - Dermal carcinogenicity
- *Chemistry, manufacturing and control*
  - Large scale manufacturing, product stability, product specifications
- *Abuse liability studies (REMs package)*

## Strategy

### TPM<sup>®</sup>/Oxymorphone Patch

- Phosphagenics has identified the studies that add the most value to the product (shown on the next slide)
- The TPM<sup>®</sup>/Oxymorphone patch has already been demonstrated to be therapeutic, as it delivers blood concentrations equivalent to the commercial oral product. The plan now is to add further value to the product to increase the magnitude of any potential deal.
- POH will begin working through some of the studies that would be required for an FDA registration. This has the following advantages;
  - Further de-risks the product
  - Reduces the work a licensee has to do prior to registration
  - FDA registration can therefore happen sooner, which saves on patent life
  - Increases the value of the product and the magnitude of a licensing deal



## Goals/Deliverables for 2014

- Begin defining product label
  - Single dose pharmacokinetic evaluation
  - Bioequivalence of different application sites and rest period before reapplication
- Non-clinical dermal toxicity study
- Complete tech transfer of patch manufacturing to GMP facility in the US
- Open IND supporting Phase II clinical study in the US
- Phase II – Efficacy versus placebo in chronic pain model in the US
- ***License! License! License!***
- Phase IIa – Oxycodone patch for neuropathic pain conducted in Australia.
- Phase II tretinoin results
- Aggressively publish in peer reviewed journals



## Goals/Deliverables for 2014

- This body of work will add significant value to the product.

But...

- It is important to realise that we are discussing the program with multiple companies in the pain space now.
- These conversations are all moving forward.
- Our aim is to license as soon as the best deal emerges from the process.