



29 May 2009

**THE MANAGER  
COMPANY ANNOUNCEMENTS OFFICE  
ASX LIMITED**

Dear Sirs

**re : PHOSPHAGENICS LIMITED  
Annual General Meeting**

Attached for release to the market is a copy of the Addresses to be given by the Chairman, Professor Andrew Vizard, and the Chief Operating Officer, Dr Esra Ogru.

Yours faithfully  
Phosphagenics Limited

Mourice R Garbutt  
Company Secretary  
poh\asx\2009 agm addresses (2) 29 05 09

**About Phosphagenics Limited**

Phosphagenics is a Melbourne-based, globally driven biotechnology company focused on the discovery of new and cost effective ways to enhance the bioavailability, activity, safety and delivery of proven pharmaceutical and nutraceutical products.

Phosphagenics' core technology is built around the science and application of phosphorylation, a process where the addition of a phosphate group has been found to enhance the bioavailability, activity and safety of existing pharmaceuticals and nutraceuticals, as well as to assist in the production of drug delivery platforms.

Phosphagenics' shares are listed on the Australian Stock Exchange (POH). An ADR – Level 1 program was established in the U.S. with The Bank of New York Mellon (PPGNY) for U.S. investors to trade in Phosphagenics' stock on the 'over-the-counter' market. In July 2007, this was upgraded to the International OTCQX, a new premium market tier in the U.S. for international exchange-listed companies, operated by Pink Sheets, LLC.

For more information, please visit Phosphagenics' web site at [www.phosphagenics.com](http://www.phosphagenics.com)

**Safe Harbor Statement**

This press release contains forward-looking statements based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialise, actual results could vary materially from the Phosphagenics' expectations and projections. Risks and uncertainties include general industry conditions and competition; economic conditions, such as interest rate and currency exchange rate fluctuations; technological advances and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; domestic and foreign health care reforms and governmental laws and regulations.

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## Chairman's Address

For many companies, 2008 was a year of extreme economic difficulties. For Phosphagenics, it was a year of solid consolidation.

Today, I will concentrate on the key strategic decisions that your Directors chose to improve the financial strength, commercial focus and efficiency of your Company.

Following my address, Dr Ogru will present technical details of our clinical program and the significant steps we took towards full commercialisation of our intellectual property.

Let me take you back to the second half of 2007, when the US sub-prime market, a word few Australians then understood, began to unravel.

At that time, your Board focused its activities to achieve three specific outcomes during 2008:

- 1) Maintain a strong cash position;
- 2) Increase investment in products with short time to market/less investment in basic research; and
- 3) Improved commercial orientation and integration of our operations.

Let me explain these in more detail.

### **Maintaining a strong cash position.**

We undertook a capital raising in early 2007 to ensure that Phosphagenics had sufficient funding to support our operations well into 2009.

In early 2008, Phosphagenics was in advanced discussions with U.S. investment bankers, planning for a North American-based capital raising. As the global financial market deteriorated further, the Board was determined not to put our strong balance sheet at risk and in May, our two major institutional shareholders participated in a share placement raising approximately \$9.1 million.

Initially, we did not receive universal market approval for this decision, but retrospectively, our decision to build up our cash position before the door slammed shut on the ability of small companies to raise money in capital markets was justified.

Raising capital was one arm of this strategy, generating cash flow and efficient use of the capital was another.

During 2008, and going forward, Phosphagenics' energies have been directed at generating a level of cash flow, within a reasonable period of time, that will allow self-sustaining business operations with minimal interference to product development.

This led to our second main focus: our product pipeline, which I will speak to in detail later.

We made other important decisions, aimed at reducing our cash burn rate and financial risk for the Company, while maintaining product development.

In particular, we decided that we would not commence any clinical trial on products – other than those already in the clinic – unless the costs are funded at least partly by a third party, or where one or more of the drugs has been licensed.

The Company finished the year with \$12.9 million in cash which, with our expected cash inflows, should enable us to continue all our programs well into 2010.

Before moving on to our product pipeline, there is one other financial matter that I will address - valuation of our intellectual property.

Every year directors of all companies are required to assess the recoverable amount of intangible assets that are held on the books.

Most biotechnology companies carry little, if any, value for patents and goodwill in their balance sheet.

But unusually Phosphagenics carries intangible assets in our balance sheet as a result of our acquisition of Vital Health Sciences in December 2004.

These acquired patent assets would normally be amortised against profits in future years once significant revenues are generated from those assets. In making their deliberation about recoverable amounts, directors must consider both internal and external sources of information, such as the carrying value compared to the market capitalisation of the company.

At the end of 2008, Directors decided to apply a conservative approach to valuing the recoverable amounts of the Company's acquired patent assets and goodwill.

Consequently, the Directors decided to decrease the carrying value of the acquired patent assets from the December 2007 value of \$123 million, to \$53.7 million.

The decrease in asset values of \$69.3 million is recognised as an expense in 2008 and has no cash impact on the Company. Goodwill was also fully written down from the December 2007 value of \$34.3 million to zero, once again with no cash impact on the Company.

Let me now move onto our next area of focus during 2008:

**Increased investment in products with short time to market/less investment in basic research**

During 2007, the Company had conclusively established the versatility of our platform technology, demonstrating that TPM could deliver both small and large molecules either into the systemic circulation or for targeted, localised delivery.

The breadth of potential use of our intellectual property is a fundamental distinguishing feature of your Company, increasing our opportunities, reducing our risks, which separates us from other biotech companies.

In 2008, we firmly put that advantage to good use.

We sought to push our portfolio towards potentially high-value pharmaceutical products with short development pipelines and lower development costs.

That decision resulted in a shift of our portfolio towards localised, rather than the systemic delivery of actives.

During 2008, using our TPM platform, we successfully initiated trials for localised delivery of retinoic acid, lidocaine and diclofenic. And going forward, much of our short-term strategic focus will be on drugs that are delivered locally.

Esra will elaborate on this activity.

On a similar vein, the costs, regulatory hurdles and time to market for the personal care products are considerably less than for pharmaceutical products.

Personal care is a substantial market with worldwide sales in the order of US\$200 billion. We will thus accelerate our personal care development in the medium term and propose to launch products within the next 12 months.

Samples of some of these products will be handed out after the meeting to those interested.

Our lead systemic delivery programs, opioids and insulin, also progressed well during 2008 and will continue to be aggressively pursued in the future.

Opioids will be moved through clinical studies, while for insulin our strategy is to optimise the formulation and develop the final product. Thus, prudently, we do not expect to return to the clinic with insulin during 2009.

Turning to our third area of focus in 2008.

### **Improved commercial orientation and integration of our operations**

As a consequence of our rapid growth during 2006 and 2007, our staff were situated at four locations in Melbourne, with the majority based at and employed by, Monash University.

During 2008, we decided to consolidate all research and development, corporate business development and administration activities into our Clayton premise.

We also wanted to boost the Company's high-level pharmaceutical and commercialisation experience.

So, in May, Fred Banti was appointed Senior Vice President and Chief Business Officer of Phosphagenics. Based in the U.S., Fred has more than 27 years' experience as a pharmaceutical executive with strong management credentials in corporate, business and strategy development, portfolio and project management.

He has held senior positions with leading pharmaceutical companies including Novartis, Pharmacia and Rhone Poulenc Rorer.

At the Board level, Michael Ashton was appointed as a Non-Executive Independent Director.

Michael has more than 30 years' experience in the international pharmaceutical industry having held senior management positions with Merck Inc., Pfizer Inc., Faulding Inc. and SkyePharma Plc, where he was CEO. Later today, as you are aware, Michael will be standing for re-election.

Dr Ogru, also standing for re-election today, was previously in charge of research and development, which involved spending much of her time at the lab bench.

At the end of 2008, Esra was appointed Chief Operating Officer, and now has a strong focus on commercialisation. Subsequently, Dr Paul Gavin was promoted to Vice President, Research and Development. Congratulations Paul.

Natural attrition has allowed us to reduce staff headcount and focus our resources in line with research and commercial priorities without redundancies.

Since this restructure, we have seen financial, cultural and workflow benefits – we are a more focussed and functional organisation with all staff understanding how their contributions relate to the Company's commercial and strategic direction. One final word about our commercialisation strategy.

Phosphagenics has always been a globally driven biotechnology company focused on the discovery of new and cost effective ways to enhance the bioavailability, activity, safety and delivery of proven pharmaceutical and nutraceutical products.

A key, consistent part of our strategy is to create alliances with leaders in their respective fields. This strategy has its downside, as dealing with global organisations takes time.

In the past we have asked for your patience on the basis that we believe the rewards will be worth the wait. We believe that your patience will shortly start to pay off.

I will now finish by providing a brief outlook for Phosphagenics.

The extreme market conditions we are all facing makes any attempt at accurate forecasting difficult, if not foolish.

The biotechnology sector faces significant challenges that Phosphagenics must be prepare for.

The Board's prudently conservative approach starting in late 2007 holds the Company in a strong position to weather a sustained downturn, while maintaining a robust commercialisation portfolio.

Over the next 12 months, we will continue to build upon our recent successes. Specifically, in 2009 we plan to:

- Complete the optimisation of our insulin formulation;
- Complete a Phase 1 clinical study investigating topical oxycodone using our new and improved formulation and apply to the FDA (Food and Drug Administration) for an IND (Investigational New Drug);
- Complete a Phase 2 clinical study for lidocaine examining the efficacy of the product for one or more indications and apply for an IND in the U.S.;
- Accelerate our personal care product development as the Company can leverage the research and development undertaken for drugs;
- At the appropriate time, pursue licensing arrangements for all of the products under development; and
- Plan to enter into arrangements to develop new products or develop their New Chemical Entities.

I will now ask Esra to provide more details of this pipeline.



"Delivering more"

Phosphagenics  
AGM 29 May 2009

Delivering Topically and Systemically

Dr Esra Ogru  
Chief Operating Officer



# Focus on Commercialisation

## Establishment of a Commercialisation & Development team:

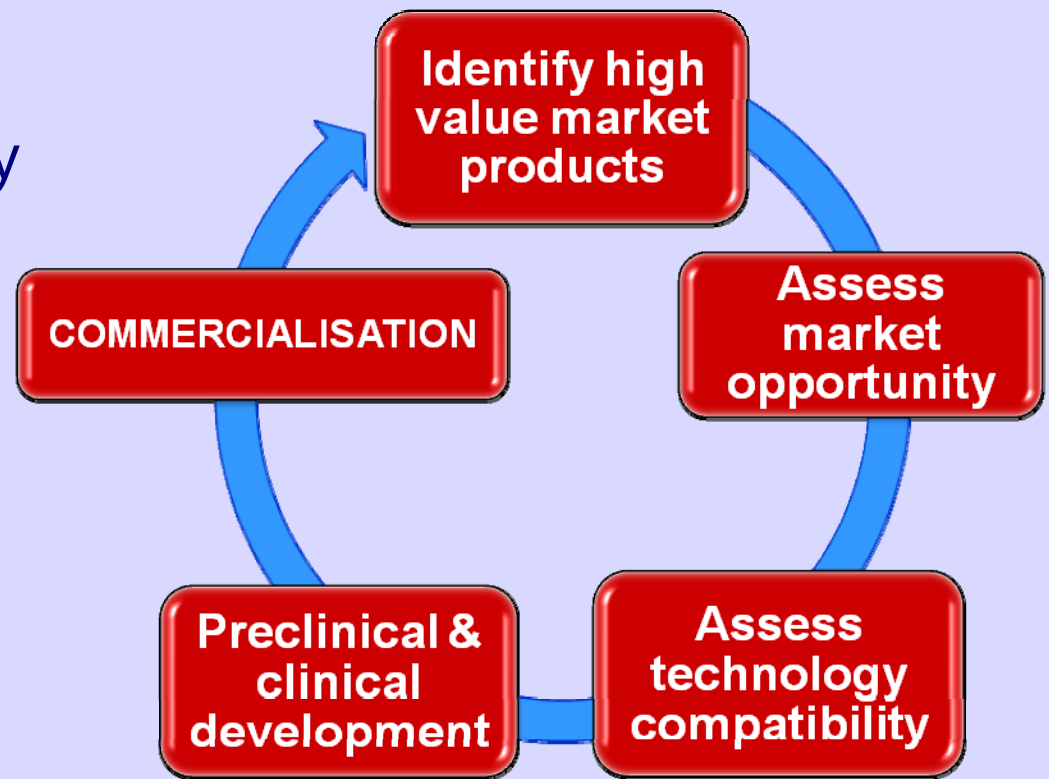
- Identify high value products
- Assess market opportunity
- Assess R&D costs
- Increase portfolio value

# 2009 Product Pipeline

## Commercial Pathway

### Strong and Targeted Commercialisation Strategy

- Development of **high value** product for large markets
- Significantly less R&D expenditure – less cash burn
- Lower risk “***fail early, fail cheap***”
- Shorter route to market



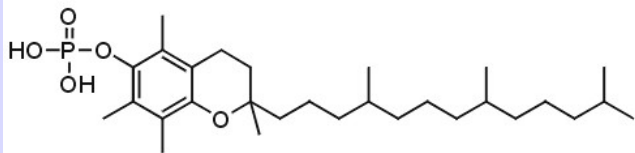
# TPM Transdermal delivery platform

## Unique Characteristics

$\alpha$ -Tocopheryl phosphate (TP)

$C_{29}H_{51}O_5P$

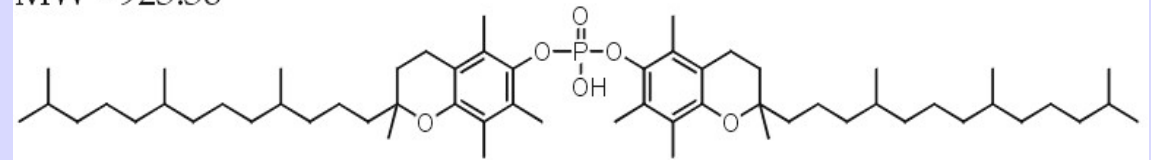
MW - 510.69



Di- $\alpha$ -tocopheryl phosphate ( $T_2P$ )

$C_{58}H_{99}O_6P$

MW - 923.38

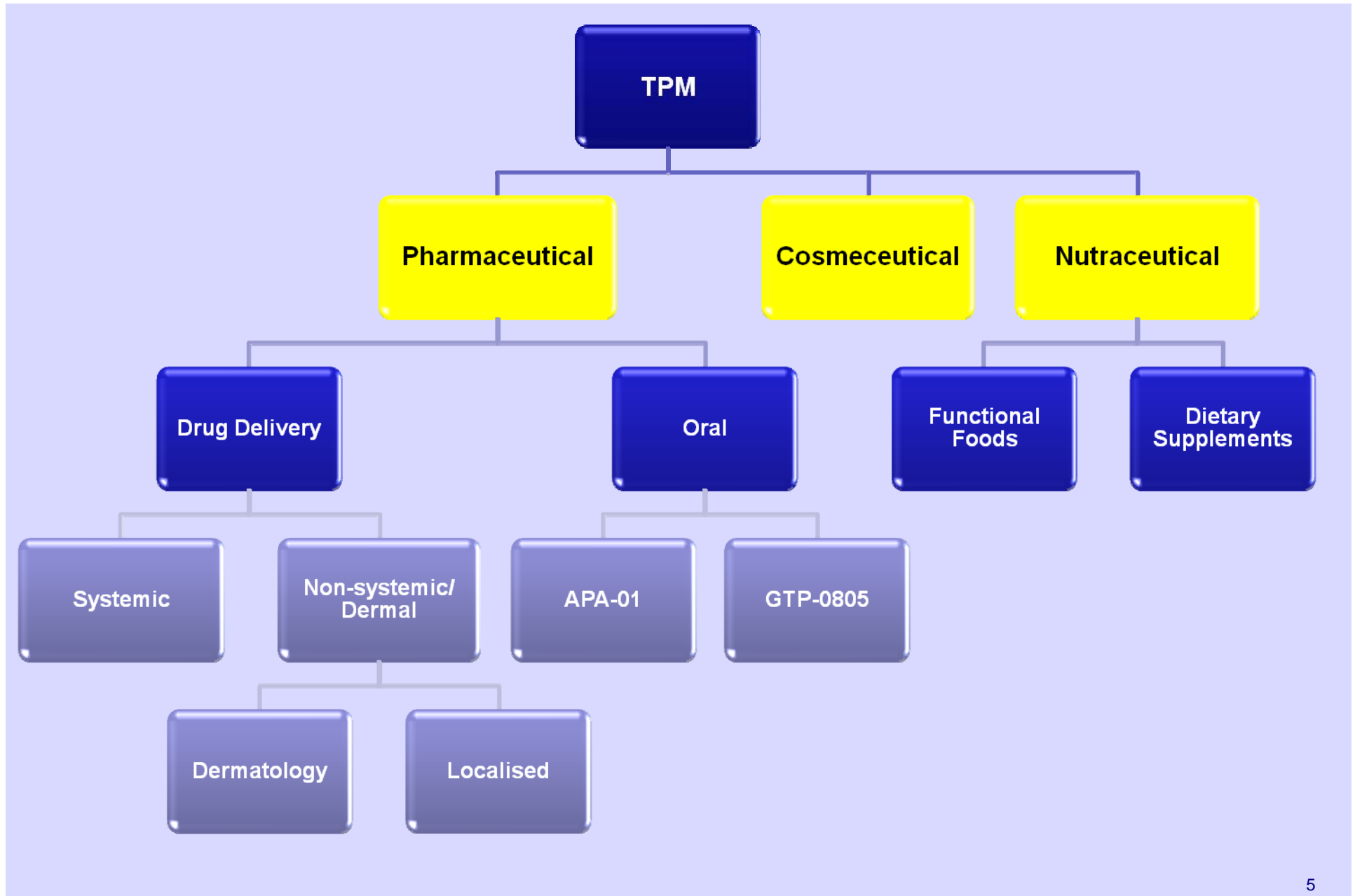


- Non-invasive
- Non-irritant
- Powerful anti-inflammatory properties

# Applications of TPM: unique delivery platform



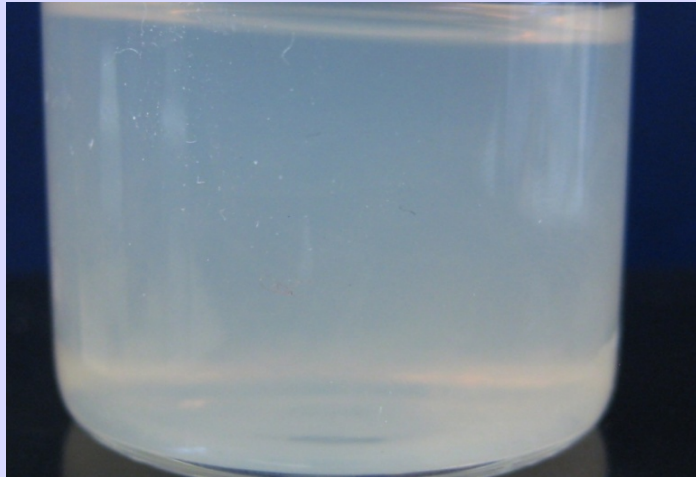
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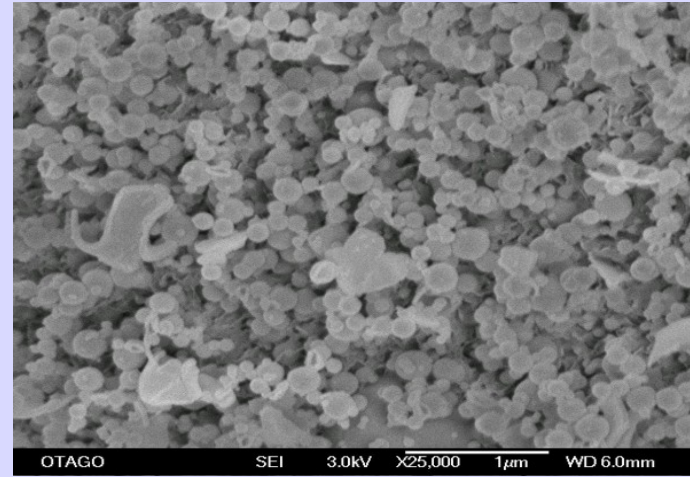
## Delivery Platforms

- Vesicular
- Micro-emulsion
- Liquid
- Patch (reservoir and matrix)
- Spray

# TPM Formulations



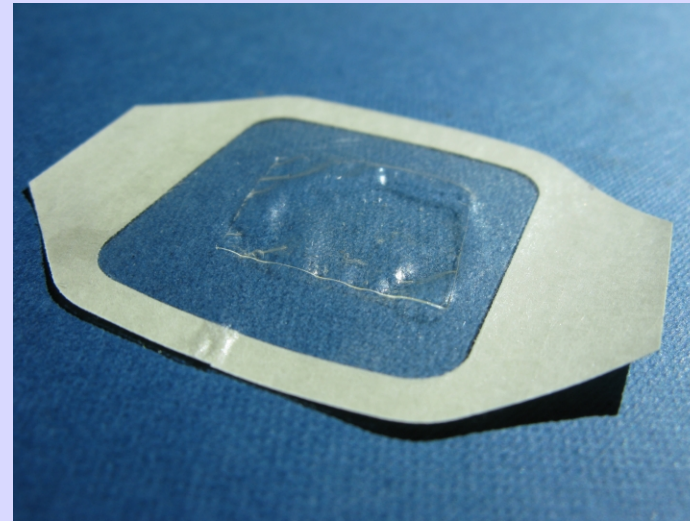
***TPM (vesicle) formulation***



***Electron microscopy of TPM***



***TPM reservoir patch***

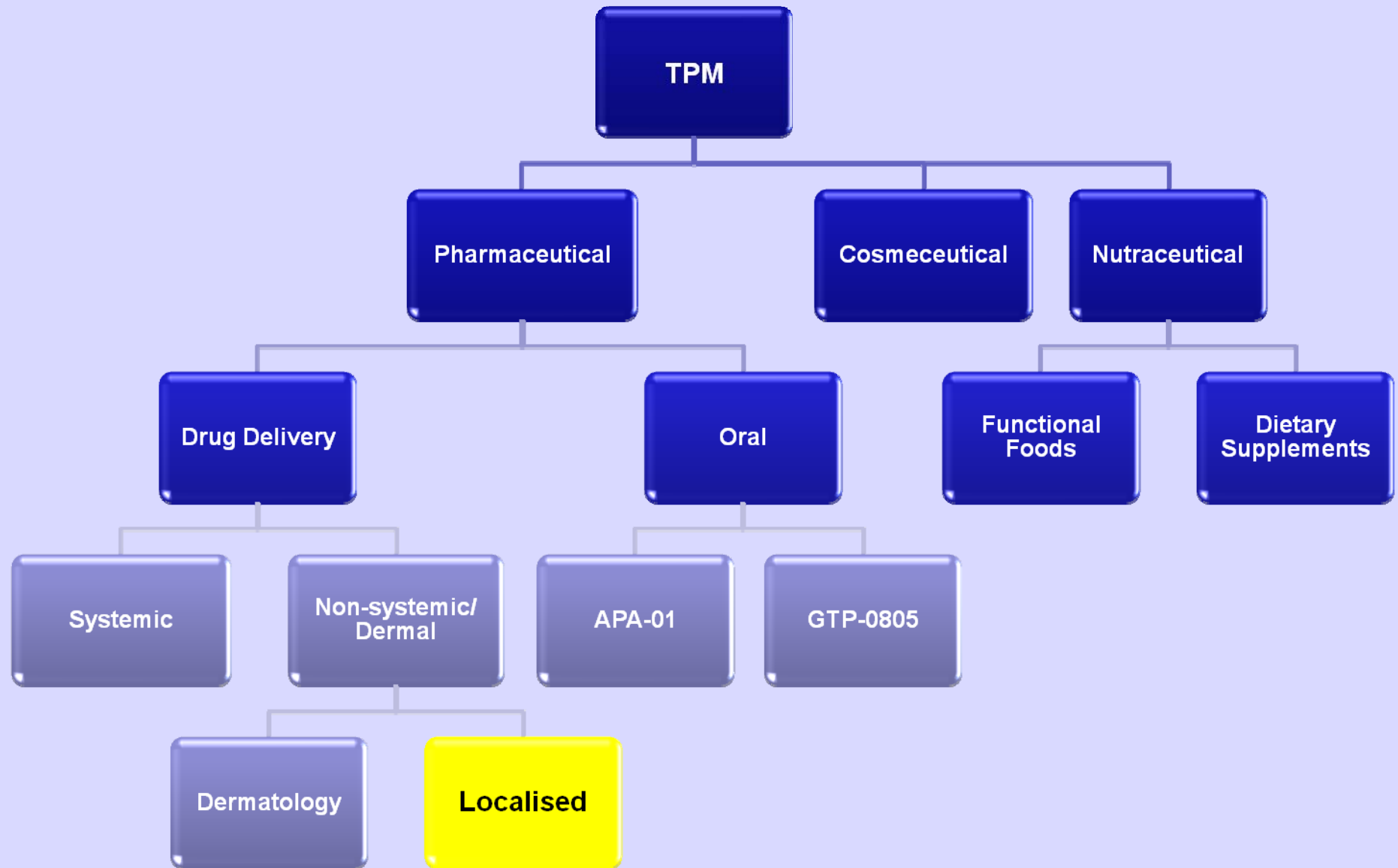


***TPM matrix patch***

# Applications of TPM: unique delivery platform



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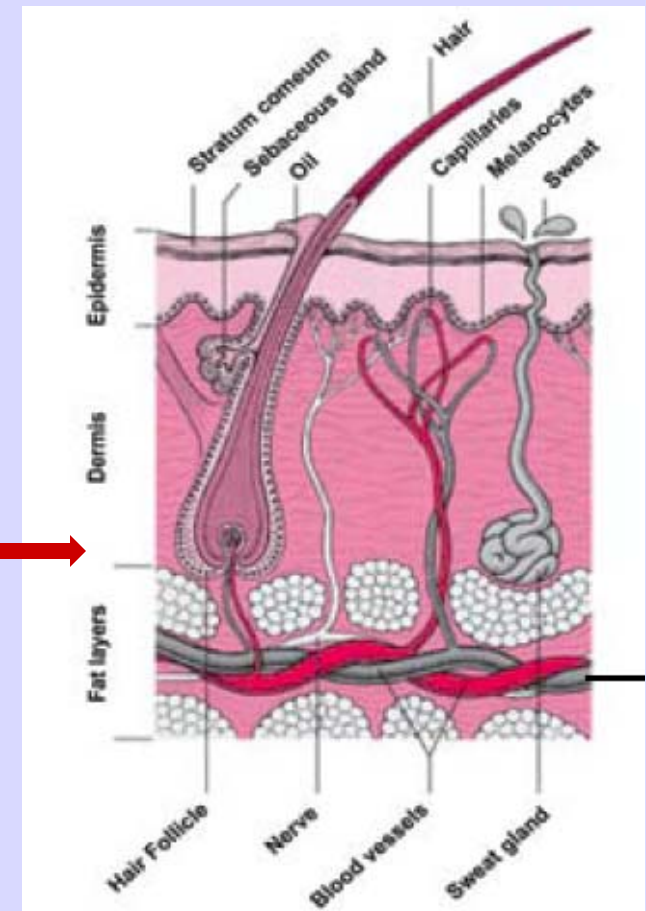


# TPM: Multiple Opportunities

Versatile technology that is unique as a penetration enhancer

With applications in:

- Non-systemic / localised delivery
- Targeted delivery
- Less R&D expenditure
- Easier route to market



# Product Pipeline



## Strong Pipeline – Targeted Local Delivery

### Lidocaine

Lidocaine is a well known topical anesthetic, sales of which exceeded **US \$1.2 billion in 2007**. It is used for a wide variety of ailments, including temporary relief of rashes, stings, sprains, strains, bites and burns.

### Retinoic Acid

Retinoic acid is the drug most often prescribed by dermatologists for topical treatment of acne. The U.S. market for topical prescription retinoids, such as retinoic acid, for the treatment of acne exceeds **US\$300 million annually**.

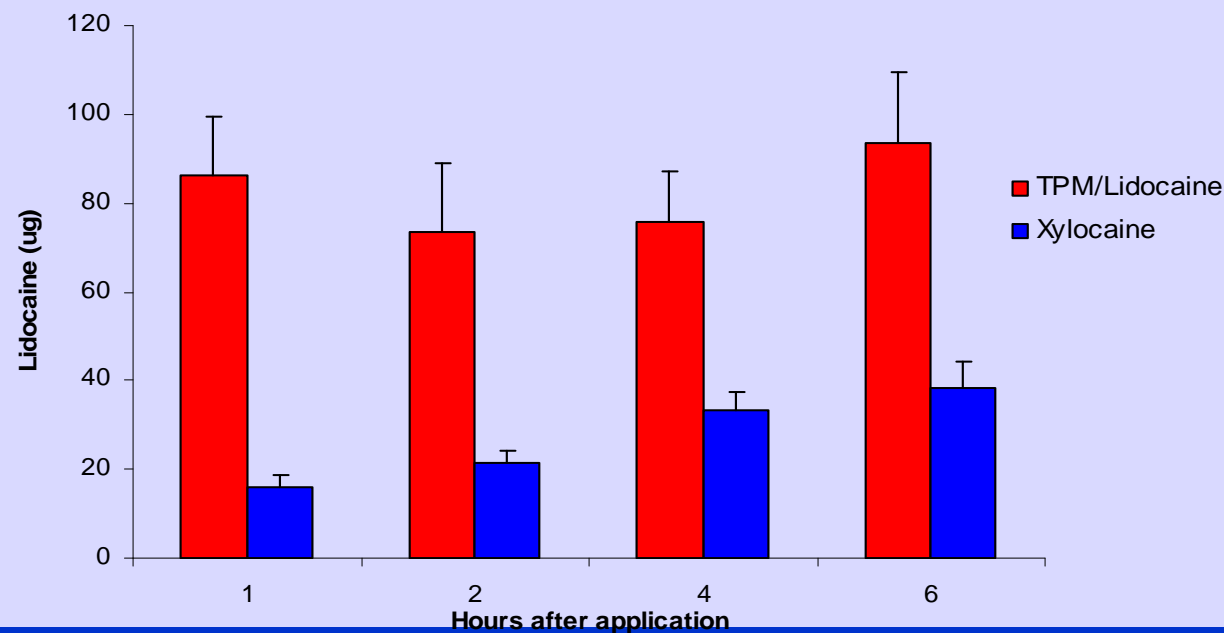
### Diclofenac

Diclofenac is a leading non steroidal anti-inflammatory drug (NSAID) widely used for sprains and strain and is commonly marketed as Voltaren®. Sales of Voltaren® in 2007 for both oral and topical application were approximately **US\$700 million**.

# TPM/Lidocaine - Clinical

## Human Clinical Trial – Dermal absorption of Lidocaine after topical application

- Equivalent dose of Xylocaine 5% ointment and TPM/Lidocaine
- N=21 tape strips taken at each time point. First strip discarded. Results from strips pooled
- N = 11 healthy volunteers, bars represent SEM

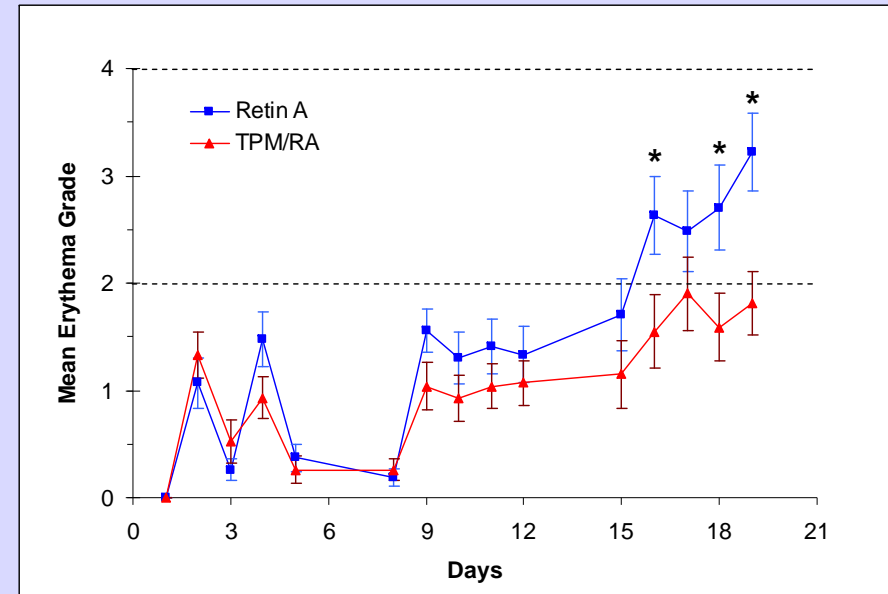
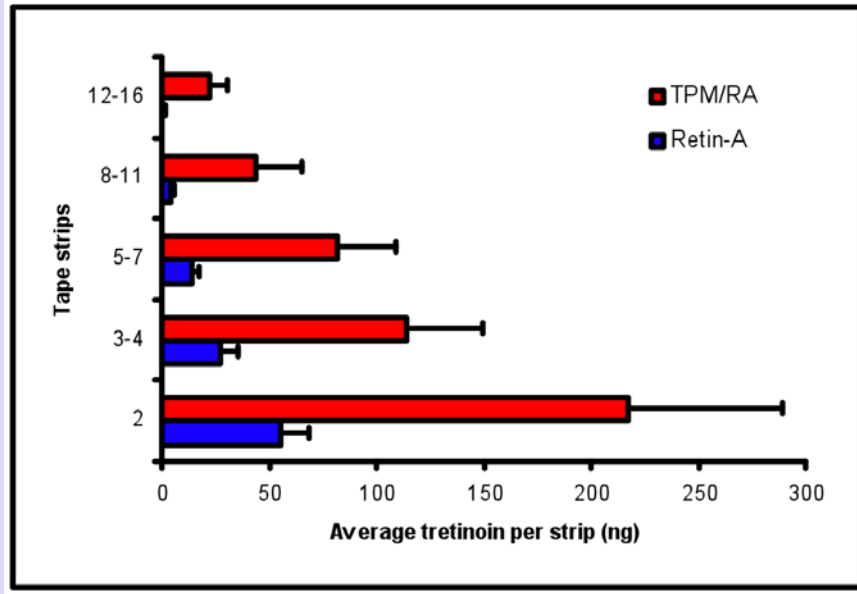


TPM/Lidocaine significantly increased dermal absorption in-vivo compared to Xylocaine ( $p < 0.001$ ).

# TPM/Retinoic Acid - Clinical



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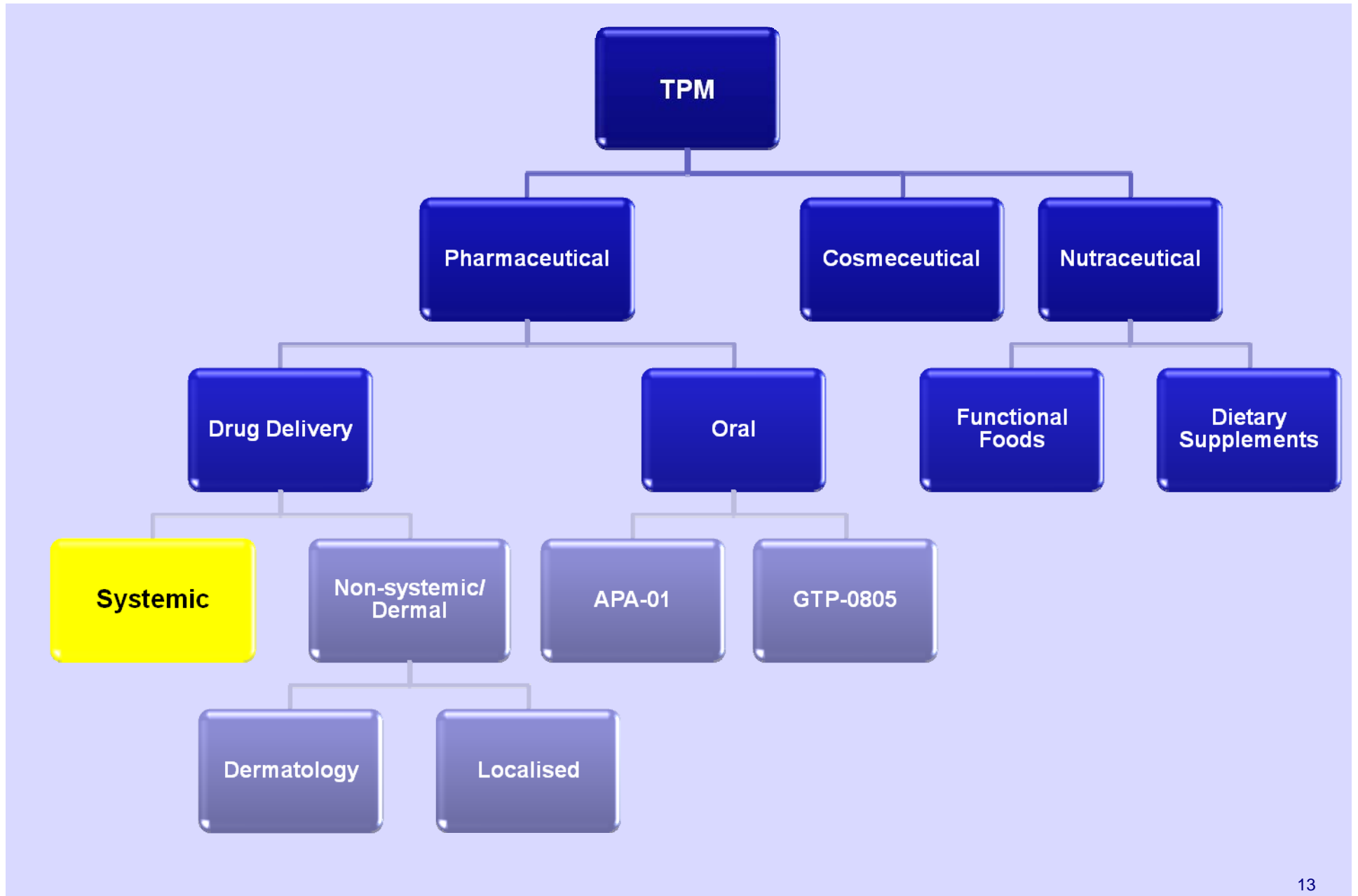


The clinical reduction of acne is dose-dependent with the amount of retinoic acid applied. However, an increased dose typically leads to increased irritation. To be able to increase the amount of retinoic acid delivered and the depth of retinoic acid penetration is important for the effective treatment of acne.

# Applications of TPM: unique delivery platform



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# Systemic Delivery



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- Large markets
- Multiple commercial opportunities
- Large R&D expenditure
- Longer route to market and registration
- Long-term goal – BLUE SKY



# UPDATE TPM/Insulin – High Value

## Overview

- Completed 2 successful phase 1 studies
- Completed a successful small phase 2 study Type 1 patients
- Safety and pharmacodynamic activity established in both studies
- Significant reductions in blood glucose, endogenous insulin and c-peptide levels from a single application of TPM/Insulin
- No irritation observed
- **PRODUCT WORKS!**

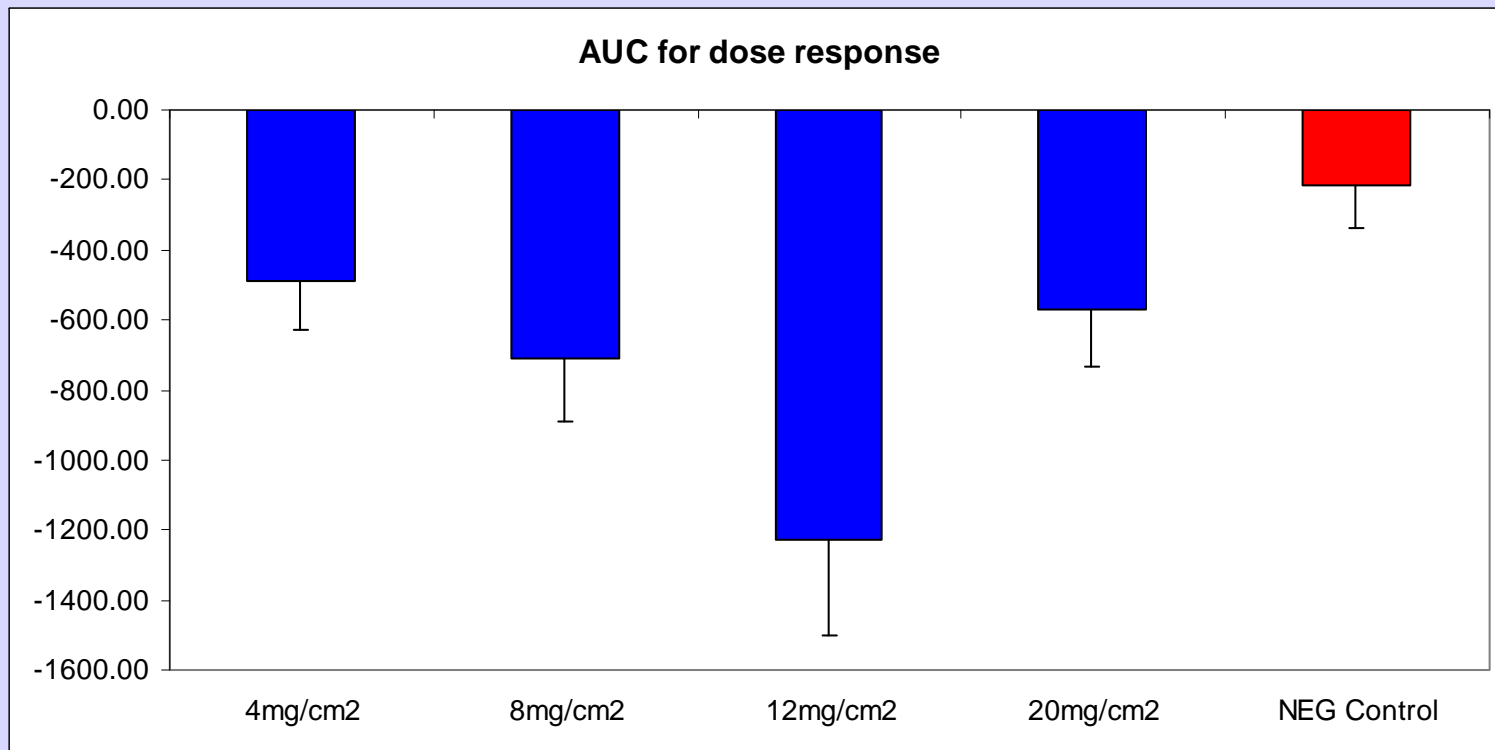
### **2009 R&D FOCUS:**

- Improve formulation
- Reduce gel volume
- Develop patch delivery system

# TPM/Insulin – Glucose lowering activity in animals

## Determining optimal dosage conditions for TPM/insulin

- Area under the curves highlight the effect of increasing dose



Optimization of dose: An application volume of ~12mg/cm<sup>2</sup> gives optimal reduction in blood glucose in the rat model

# TPM/Oxycodone - Update



TPM/Oxycodone is a world first – currently there is a very large unmet medical need for non-invasive, sustained opioid delivery.

- Completed all preclinical studies
- Developed (in-house) patch systems
- Preparing for clinical studies
- In commercial discussions

# Development Status



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- GRAS status approved ✓
- Strong Clinical Pipeline ✓
- TPM/Lidocaine Phase 1 safety and tolerability study ✓
- TPM/Diclofenac Phase 1 safety and tolerability study ✓
- TPM/RA Phase 1 safety and tolerability study ✓
- TPM/Insulin Phase 1 safety and tolerability study ✓
- TPM/Insulin Phase 2 – development on track ✓
- TPM/Oxycodone Patch and Gel technology in development on track ✓

# Nestle UPDATE

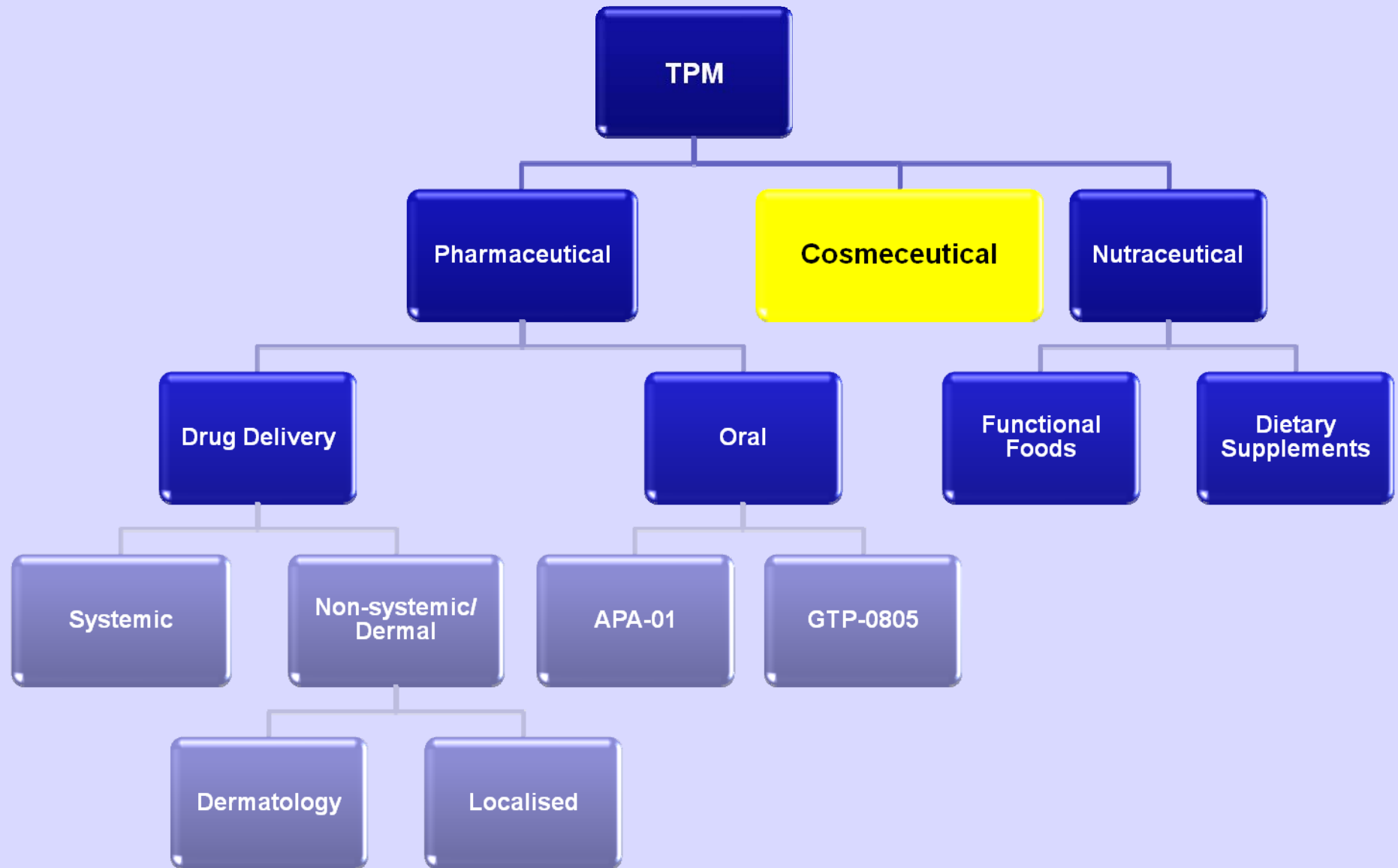


- Multi-site phase 2 completed in April 2009
- Initial data sent to Nestle
- Analysis of data still under way

# Applications of TPM: unique delivery platform



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# Total E – Skin Care Range

Pharmaceutical research has proven that there are positive benefits of TPM for skin.

These include:

- Anti-redness
- Anti-acne
- Promote healing

Logical next step.....

# Total E – Skin Care Range

Establishment of a unique range of skin care products which is backed up by real science:

- Anti-ageing face cream
- Concentrated anti-oxidant serum
- After sun care
- After shave skin balm

**Products aimed at the high end consumer**

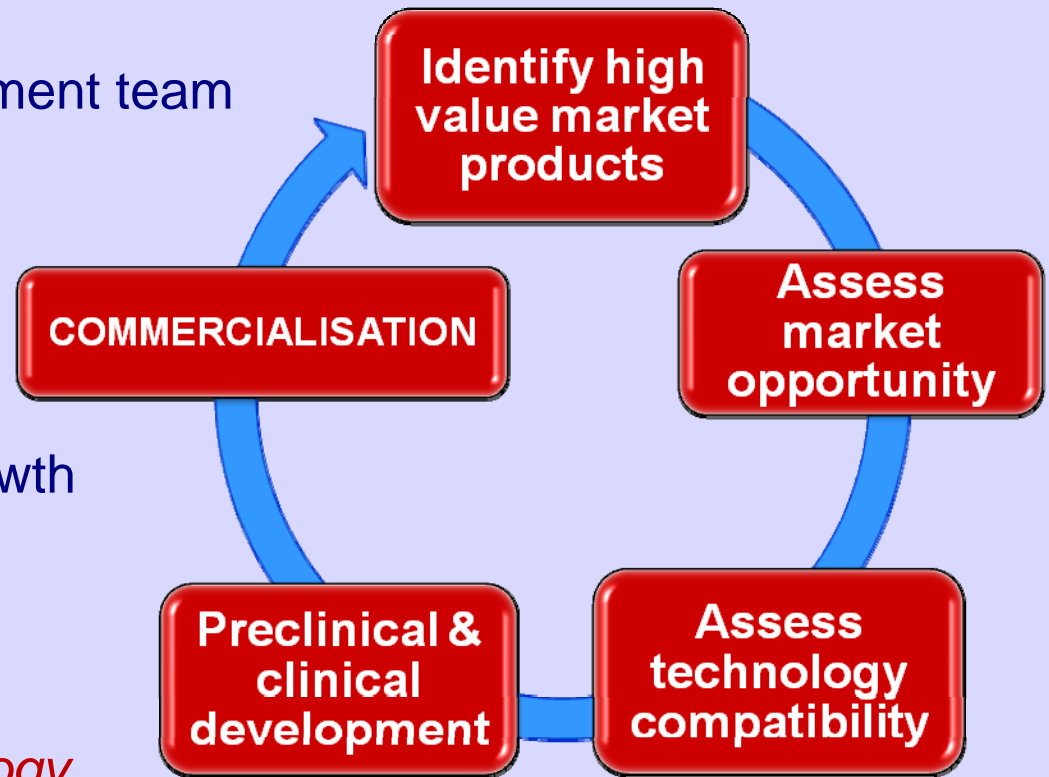


# Moving forward.....



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- Strong management & development team
- Commercial focus
- **High value products in high value markets**
- Short term return, long term growth
- Maximising on investments



*KEY: Unique and versatile technology*

# Phosphagenics R&D



## Pharmaceutical

<b>Drug delivery – systemic</b>	<b>Pre-clinical</b>	<b>Phase I</b>	<b>Phase II</b>
<b>Insulin</b>	Complete	(Aus) Phase 2a study	IND/Phase 2B
<b>Oxycodone (gel)</b>	Complete	Being prepared	
<b>Oxycodone (patch)</b>	Underway		
<b>Drug delivery – local</b>	<b>Pre-clinical</b>	<b>Phase I</b>	<b>Phase II</b>
<b>Lidocaine</b>	Complete	Complete	Being prepared
<b>Diclofenac</b>	Complete	To be repeated	
<b>Retinoic Acid</b>	Complete	Complete	Being prepared
<b>NSAID + Lidocaine</b>	Commence mid year		



"Delivering more"

Phosphagenics

THANK YOU