Mayne Pharma Group Limited

Company Presentation
Nomura Biotech Conference
26th July 2011

Dr Roger Aston
Chief Executive Officer

Mayne Pharma Group Limited

Summary

- Leading Australian specialty pharmaceutical company
  - acquired F. H. Faulding oral-dose facility in 2009
  - ASX listing in 2007 (previously known as Halcygen Pharmaceuticals Ltd)
- Successful history in the drug delivery market
- Proven track record of developing, manufacturing and commercializing improved drug formulations in FDA, TGA, EMEA approved facility
- Portfolio of market leading products utilising proprietary drug delivery systems (controlled release, taste masking, improved bioavailability)
- Long standing relationships with international pharmaceutical organisations

Established product portfolio & partnerships

Product Portfolio (core products)

DORYX®
(Doxycycline Hyclate
Delayed-Release Tablets, USP)
75 mg, 100 mg and 150 mg

KADIAN®
Morphine Sulfate Extended-Release Capsules
20 mg • 30 mg • 50 mg • 60 mg • 100 mg

Kapanol® (morphine sulfate)

In-market global sales of developed products ~ US$ 500M p.a.

Pharmaceutical Partners (marketing partners, contract clients)

Warner Chilcott
GlaxoSmithKline
Abbott
sanofi aventis
Because health matters
Cephalon
INSIGHTS INTO MEDICINE®
Pfizer
MEDA
Care Pharmaceuticals

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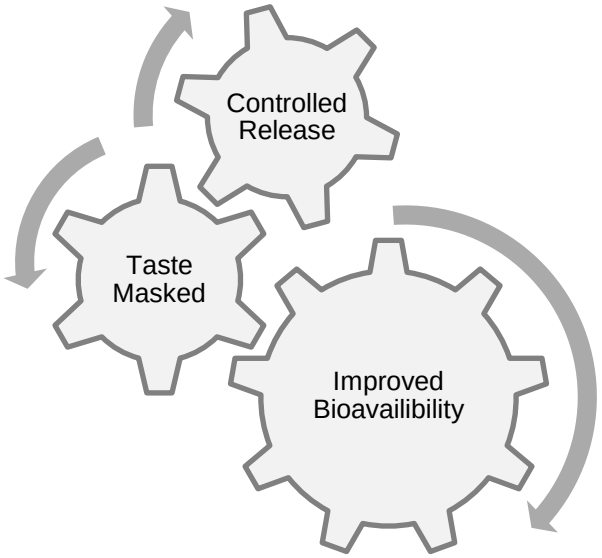
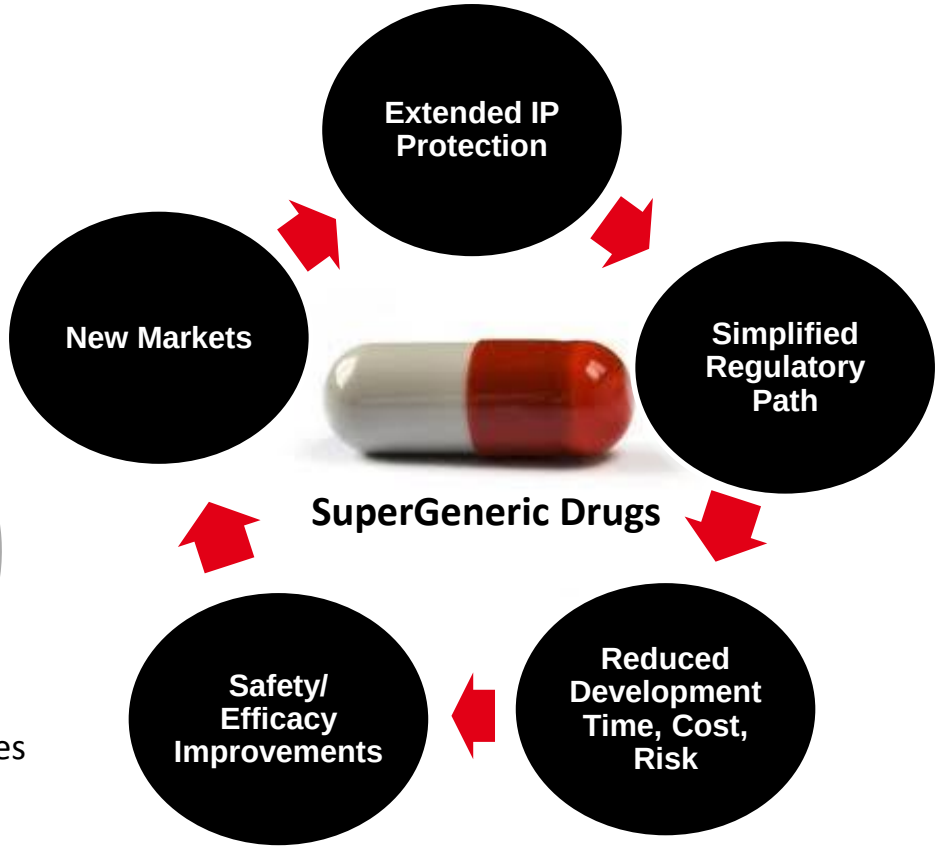
Drug development - SuperGenerics

Proven Drugs



Proprietary Drug Delivery Technologies



proprietary improvements of existing drugs creating next generation pharmaceuticals

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Proprietary delivery technologies

Controlled Release Delivery Systems	**Sustained Release**	Steady levels of drug concentrations over 12-24 hrs following a single dose
	Modified Release	Immediate release of a small portion of drug followed by the delayed release of the balance
	Pulsed Release	Pulse release of drug over 12-24 hrs following a single dose
	Delayed Release	Targets the drug to a specific site in intestinal tract, particularly avoiding release in the stomach
SUBA®	**Improved Bioavailability**	Particularly for poorly soluble drugs (SUBA®)
Clean-taste®	**Taste Masked**	Allows drugs to be more palatable and easier to swallow (Cleantaste®)

Product pipeline

Therapeutic Area	Formulation	Phase 1	Phase 2	Phase 3	Filing for Approval	Registration	Marketing	
Infection	Doryx®						Warner Chilcott (US) **Available for licensing (ex-US)**	
Infection	Eryc®						Pfizer (Canada), Boryung (Korea), Meda (Sweden, Norway), Cephalon (UK)	
Infection	SUBACAP®						**Available for licensing**	
Infection	Minocycline		Delayed Release				**Available for licensing**	
Pain	Kapanol®/Kadian®						Abbott (Canada), Actavis (US) GSK (AU, EU)	
Cardiovascular	Astrix®						Boryung (Korea), DKSH (Singapore), Akbar Pharma (Sri Lanka), PM Pharma (Malaysia)	
Cardiovascular	Metoprolol		Generic to TOPROL-XL				**Available for licensing**	
Cardiovascular	Diltiazem		Generic to CARDIZEM-CD				**Available for licensing**	

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Doryx®

Summary

- The only doxycycline formulation containing enteric-coated delayed release pellets designed to minimise nausea whilst still providing therapeutic blood levels of doxycycline
- Leading branded oral tetracycline in the US - Warner Chilcott #1 market share by value (US$ 200 million)
- Targeting the global acne market (US$ 5 billion)
- Leverage the success in the US to other markets (Asia, Latin America)

Doryx®

US update

- FY11 has been a challenging year for Doryx® with sales down 47% as a result of FX and a reduction in pipeline inventories by Warner Chilcott
- Vigorously defending patent which underpins marketing exclusivity for Doryx® in the US
  - Subject to Paragraph IV challenges
  - Out of court settlement with parties progressing
- Life cycle management of Doryx® into new dosage forms is continuing following FDA rejection of a dose strength

Astrix®

Summary

- Astrix® number 1 prescribed low dose aspirin in Australia
- Delayed release, low dose aspirin indicated for chronic use in the treatment of cardiovascular or cerebrovascular disease
- Astrix® capsules are the only enteric coated pelletised form of low dose aspirin in the market. Astrix® is sold in Australia, Hong Kong, Korea and Singapore
- New consumer focused website www.astrixaspirin.com.au launched
- Partnership with HealthOne to promote Astrix® brand of products in pharmacies in Australia

Kadian® / Kapanol®

Summary

- Sustained release morphine used in the management of chronic pain
- Kadian® / Kapanol® is sold in Australia, Canada, Japan and various European countries
- In the US, Kadian® is sold by Actavis (Market value $200m) – patent expired
- Exploring partnership opportunities internationally

SUBACAP®

Summary

- Super-bioavailable itraconazole
- Reliable, effective broad spectrum anti-fungal drug
- Near market in-licensing opportunity
- Active program to secure marketing partners in all territories

SUBACAP®

Product

- Significant improved formulation of itraconazole (J&J - Sporanox®) based on SUBA® technology
- Sporanox® hampered by erratic/unpredictable clinical response (poorly controlled absorption) and safety issues
- SUBACAP® formulation provides for significantly less variable drug absorption (fed/fasted state)
- Less intra/inter patient variability, more predictable clinical response with increased efficacy and potential for reduced toxicity (blood concentrations similar to Sporanox® at half the dose; 50mg vs 100mg

SUBACAP®

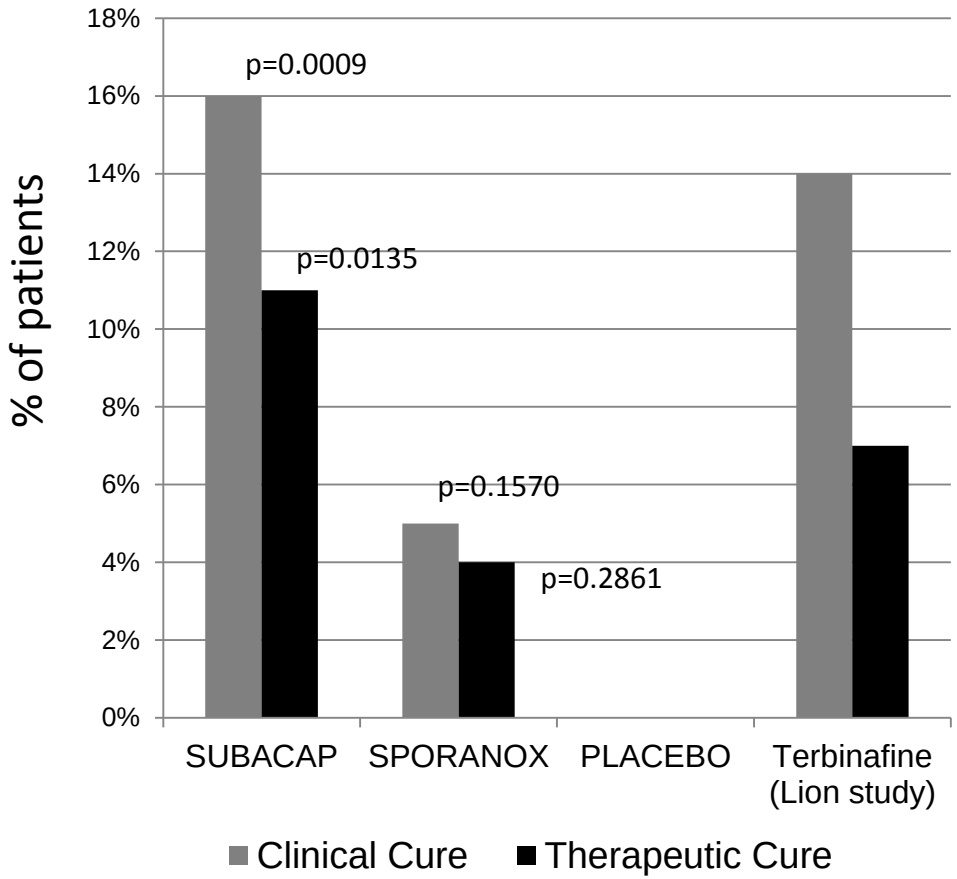
Market potential

- Targeting the global itraconazole market (US$ 0.6 billion, 2010)
- Potential for reach through into terbinafine (Lamisal®) market (currently $700M)
- Initial target indication Onychomycosis (US$ 3.6 billion, 2010)
- Broad label claim strategy
  - Candidosis, Dermatophytoses, Aspergillosis, Histoplasmosis….
  - Maintenance therapy in AIDS
  - Transplant recipients
  - Prevention during prolonged neutropenia

Comparison of SUBACAP® and Sporonox®

Attribute	SUBACAP®	Sporanox®
Percent absorbed	95%	55%
Dose	100 mg	200 mg
Capsule strength	50 mg	100 mg
Capsule size	Medium	Large
Food effect	Take without regard to meals	Take with food to increase absorption
Absorption in achlorhydric patients	Unaffected	Absorption reduced (>20%)
Variability of absorption within and between patients	Low	High
Safety / Efficacy	Improved over generics	Generics

Effective – Multi-centre US Phase II Onychomycosis study



- 100 mg SUBACAP® before food vs 200 mg SPORANOX® after food; 12 weeks
- Results at study completion (week 24)
- Number of patients = 175
- SUBACAP® significantly superior to PLACEBO for both efficacy endpoints
- SPORONOX® not significantly different to PLACEBO
- PLACEBO results = 0 cures
- No significant difference in side effects

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SUBACAP®

Development and regulatory status

- Six post-IND PK studies completed (AU, US, EU)
- Positive 175 patient US multi-centre Phase II trial (Onychomycosis)
- Commercial manufacturing established (FDA-audited facility)
- Europe - MAA filed Nov 2010 (UK ref state)
- US – 505(b)2, End of Phase II meeting (Type B) scheduled August 2011

Business strategy for growth

Optimising current business

- Expansion into new territories/markets
- Vigorous defense against generic competition
- Improved manufacturing efficiencies
- License technologies

Product development

- Life cycle management - new dose strengths, formulations
- New drug development (ICEs)

Corporate development

- Company acquisitions
- Leveraging partnerships
- Joint ventures

Portfolio expansion

- In-license/acquire branded products
- IP and/or market/regulatory exclusivity
- Sales and Marketing expansion