



Mayne Pharma Group Ltd

Company Presentation

Australasian Life Science Investment Summit 2011

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www.maynepharma.com



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Company Profile

- Leading Australian specialty pharmaceutical company
 - Acquired F.H. Faulding oral-dose facility in 2009
 - ASX listing in 2007 (previously Halcyon Pharmaceuticals Ltd)
 - Successful history in the oral drug delivery market
 - Proven track record of developing, manufacturing and commercializing improved drug formulations in FDA/TGA/EMA approved facility
 - Portfolio of market leading products
 - Focused on the development of ICE's ("SuperGenerics")
 - Utilising proprietary drug delivery systems (CR, improved BA, taste-masking)
 - Reduced development time/cost/risk and simplified regulatory path (e.g., 505(b)2)
 - Highly experienced Board and Senior Management Team
- www.maynepharma.com

Recent Highlights

➤ **FY 2011 Group revenue A\$ 50.1M / underlying EBITDA A\$ 9.2M**

- New business development initiatives underway and business restructured to improve efficiencies and increase capacity utilisation

➤ **SUBACAP® (SUBA®-itraconazole)**

- EU MAA filed Nov 2010 - anticipate approval FY 2012
- US 505(b)2 - EoP2 meeting with FDA - Phase III program planning underway
- Significant interest from a range of potential licensing partners

➤ **Doryx®**

- 2010 Warner Chilcott US sales US\$ 172M (leading branded oral tetracycline in US)
- Vigorously defending “161 Patent” which underpins exclusivity in the US (expiry 2022) – subject to Para IV challenges (out-of-court settlements progressing)
- Preliminary injunction against Mylan launching generic version Doryx® 150mg tablet and FDA approval of Doryx® 150mg dual-score tablet



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)



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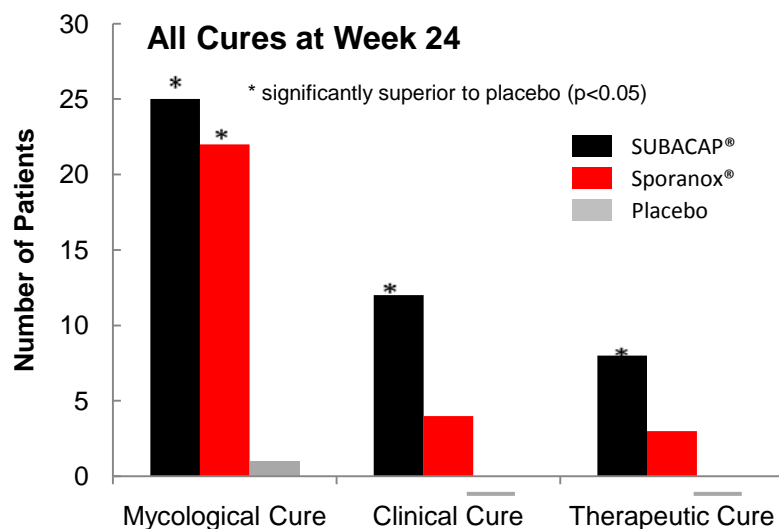
Product Profile

- Significantly improved formulation of itraconazole (J&J - Sporanox®) based on proprietary SUBA® technology (50mg capsule)
 - Granted US and AU patents (under examination EU, JP, CAN) - expiry 2021
 - Additional patent filed 2011, potentially extending exclusivity to 2032
- Sporanox® hampered by unpredictable clinical response (poorly controlled absorption) and safety issues
- SUBACAP® offers a clear competitive advantage
 - Improved absorption (95% vs 55% Sporanox®)
 - Less variable PK profile - less intra/inter patient variability (fed/fasted state)
 - Predictable clinical response with increased efficacy
 - Potential for reduced toxicity (blood concentrations similar to Sporanox® at half the dose (50mg vs 100mg)
 - Effective in achlorhydric patients

Development and Regulatory Status

- Six post-IND PK (bioequivalence) studies completed (AU, EU and US)
- Positive 175 patient US multi-centre Phase II trial (Onychomycosis)
- Commercial manufacturing established (FDA-audited facility)
- Europe - Article 10(3), Directive 2201/83/EC
 - MAA filed Nov 2010 (UK Reference Member State)
- US - 505(b)2
 - Division of Dermatology & Dental Products / Special Pathogens Transplant Products
 - EoP2 meeting with FDA August 2011
 - Phase III trial design underway (pre-Phase III meeting with FDA expected Dec 2011)

Multi-centre US Phase II Onychomycosis study



Mycological Cure	Negative stain and culture
Clinical Cure	Nail rating score of 0
Therapeutic Cure	Both of the above
Nail rating score	0 if <10% of the nail is missing, no thickening and no discoloration

- SUBACAP® significantly superior to Placebo for all endpoints
- Sporanox® not significantly different to Placebo for clinical/therapeutic cure endpoints

Market Potential and Commercialisation Strategy

- Targeting the global itraconazole market valued at US\$ 0.6B¹ with a premium-priced ICE (“SuperGeneric”) with potential for reach through into terbinafine (Lamasil®) market valued at US\$ 0.7B¹
 - KOL and payer acceptance of value/clinical benefits
- Initial target indication – Onychomycosis (US\$ 3.6B)
 - Onychomycosis the largest source of global itraconazole prescriptions
 - 35 million patients in the US alone represents a large and growing market
- Broad label claim strategy being pursued
 - Candidosis, Dermatophytoses, Aspergillosis and Histoplasmosis
 - Maintenance therapy in AIDS, transplant receipts, prevention during neutropenia
- **Partnering program initiated to identify/secure marketing partner(s)**
 - Significant discussions with potential global marketing partners on-going

¹IMS Health and Thomson Reuters reports

Financial Summary (14 October 2011)

- ASX ticker: MYX
- Current Share Price: A\$ 0.39 (14 October 2011)
 - 52 week high: A\$ 1.00, 52 week low: A\$ 0.30
- Shares on issue: 151M
- Market capitalisation: A\$ 59.1M
- FY 2011 Results
 - Revenue : A\$ 50.1M
 - Gross Profit : A\$ 23.2M
 - Underlying EBITDA : A\$ 9.2M
 - Cash on hand : A\$ 5.8M



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