



Mayne Pharma Group Limited

FY11 Annual General Meeting
23rd November 2011

Mr Roger Corbett

Chairman

Dr Roger Aston

Chief Executive Officer

www.maynepharma.com





Agenda

- Chairman's address
- Chief Executive Officer's presentation
- Formal business
 - Financial report
 - Re-election of Directors
 - Remuneration report



Executive Summary

Doryx®

- Challenging 12 months for Doryx® with US sales down 46%*
- New dual-scored Doryx® 150mg tablet launched in US
- Doryx® has maintained marketing exclusivity in the US post expiry of 30 month stay

SUBACAP®

- SUBACAP® on track for approval in the EU during FY12
- Phase III trial to be completed in the US

Other products

- Sales of other products were up 18%*
- New business development initiatives expanding product mix and distribution reach

Stable financial position

- Debt now completely paid down; new facilities in place if required
- Business restructured to improve efficiencies and increase capacity utilisation

* On the full 12 month FY10 result



FY11 group results

- Sales and earnings down on annualised FY10 result

		<u>FY10 Reported</u> 8 month contribution MPI
– Total revenue	\$50.1m	\$36.7m
– Gross profit	\$23.2m	\$18.5m
– Reported EBITDA	\$7.9m	\$8.5m
– Reported NPAT	\$1.7m	\$3.3m
– Reported EPS	1.1cps	2.6cps
– Underlying EBITDA	\$9.2m*	

* After adjustments. Includes \$1.1m provision for the value of Doryx® inventory yet to be approved by the FDA, \$0.8m non-cash reduction in the earnout liability and one-off redundancy costs of \$1m for the restructure of the Salisbury production site



Balance sheet and cash flow stable

- Total assets of \$53.7m (30 June 2011), including \$5.8m cash, \$21.5m property, plant & equipment and \$12.8m inventory & receivables
- US\$ debt completely paid down in October
- Carrying value of the earn-out to Hospira is \$15.1m with 5 remaining payments
 - Paid on calendar year revenue in February
 - FY11 payment of \$6.6m representing instalment for the 2010 calendar year
- Although no final dividend declared the Board will review at each half after assessing the Company's operating performance and outlook at that time



Business strategy for growth

Existing products

Improve formulations

- Maintain a product life-cycle management program to stay ahead of potential competition
- New dose strengths and improved formulations of many existing products under development

Defend & expand markets

- Vigorous defense against generic competition
- Expansion of proprietary products into new markets / territories
- Expanded sales and marketing effort of the Australian proprietary product portfolio

New products

Develop / in-license / acquire /

- Development and commercialisation of Mayne Pharma's portfolio of partially completed products
- Develop new products (Improved Chemical Entities / "ICEs") that utilise Mayne Pharma's proprietary drug delivery systems
- Identify new product opportunities for in-licensing / acquisition



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Key milestones

Achieved

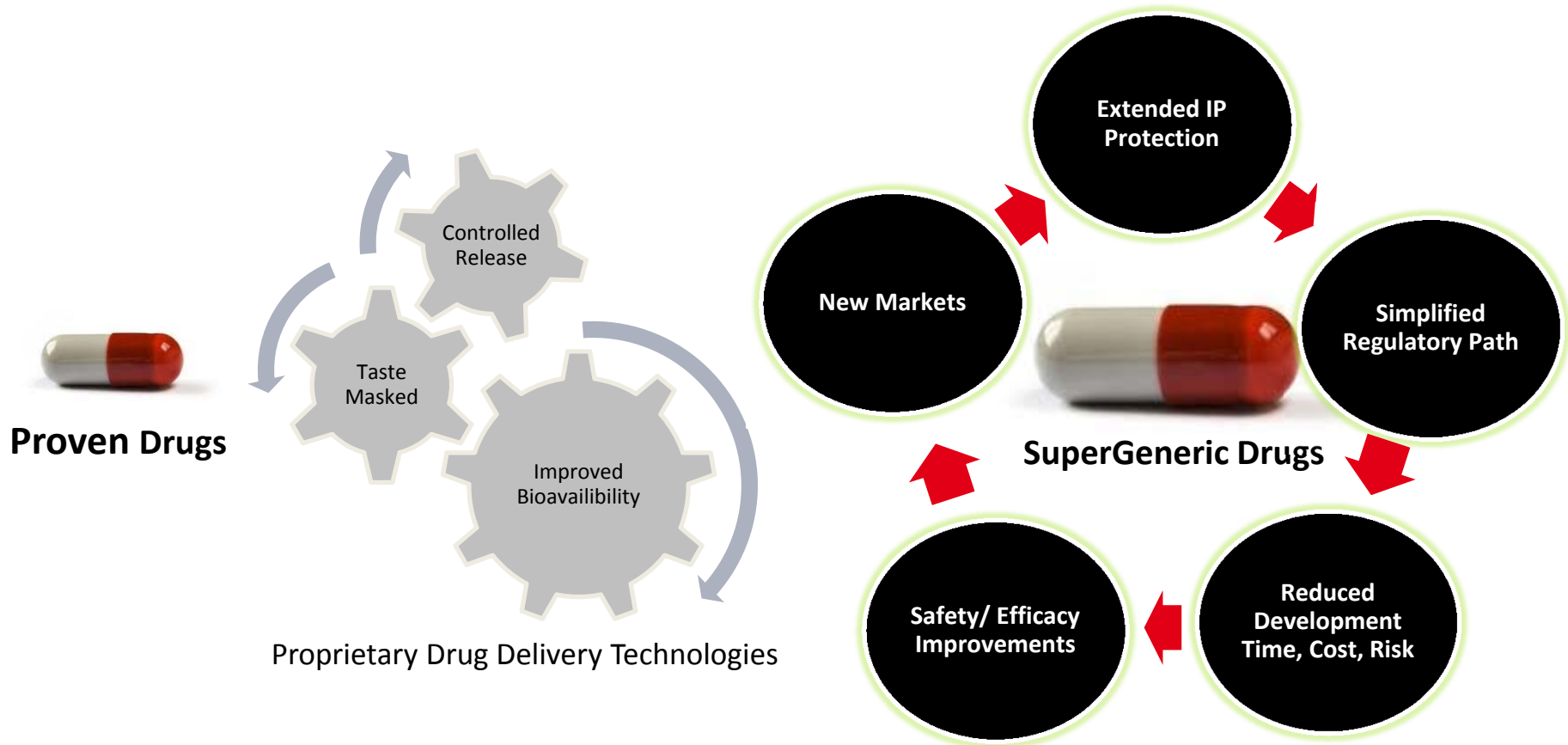
- SUBACAP[®] dossier lodged in the EU
- Successful Phase II trial of SUBACAP[®] in the US
- Doryx[®] maintaining marketing exclusivity in the US
- Maiden dividend and special dividend paid
- Debt paid down
- Restructured business to deliver ongoing savings

Ongoing

- Appointment of marketing and distribution partners
- SUBACAP[®] Phase III trial in the US
- Regulatory approval of SUBACAP[®] in EU and ROW
- Clarity around Doryx[®] patent exclusivity
- Develop / in licence / acquire new products



Proprietary drug development program



*proprietary improvements of existing drugs
creating next generation pharmaceuticals*



SUBACAP®



- Super-bioavailable itraconazole
 - Significant improved formulation of itraconazole (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)
- Reliable, effective broad spectrum anti-fungal drug
- Significant interest from a range of potential licensing partners



SUBACAP[®] broad-spectrum antifungal

	FUNGAL INFECTIONS				
	Histoplasmosis	Aspergillosis	Onychomycosis	Candidiasis	Cryptococcus
Itraconazole	✓	✓	✓	✓	x
Fluconazole	x	x	x	✓	✓
Posaconazole	x	✓	x	✓	x
Voriconazole	x	✓	x	✓	x
Terbinafine	x	x	✓	x	x

Itraconazole's broad-spectrum makes it a good choice when the fungal species being treated has not been identified

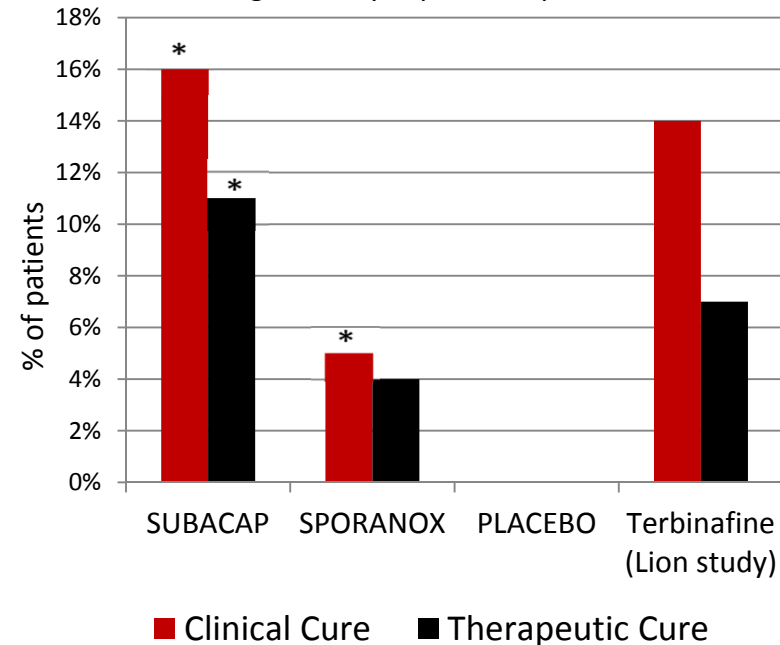


SUBACAP[®] – Phase II study

- Significantly improved formulation of itraconazole based on SUBA[®] technology
- SUBACAP[®] significantly superior to placebo at both efficacy endpoints
- SPORANOX[®] not significantly different to placebo
- Placebo had no cures

All cures at Week 24

* Significantly superior to placebo



Mycological cure - negative stain and culture

Clinical cure – nail rating score of 0 (<10% of the nail is missing, no thickening and no discoloration)

Therapeutic cure – clinical cure and mycological cure

Source: Company data on file



SUBACAP® – Regulatory update

Europe

- Collaborating with MHRA to address its evaluation questions, with approval anticipated in FY12
- Launch FY12 subject to approval and appointment of marketing and distribution partner

US

- Pre-phase III meeting requested with the FDA to confirm the scope of the clinical trial
 - Phase III onychomycosis trial in ~700 people

Rest of World

- Meeting scheduled with the TGA for January 2012
- Following EU approval, dossier used to support the regulatory process in select Asian and South American countries



SUBACAP[®] – Development update

- New dose forms in development
- Line extensions under review
- Manufacturing equipment for commercial supply currently being installed at Salisbury facility



Doryx®



- Dual-scored Doryx® 150mg tablet approved and launched in the US
- Injunction against Mylan prevented launch of a generic Doryx® following the expiry of 30 month stay in September
 - US District court found a reasonable likelihood that the Doryx® 161 patent is valid and infringed by Mylan's generic product
 - Citizen petition filed with FDA and awaiting response
 - Court date to determine validity of Doryx® 161 patent expected 1Q 2012
- Continuing to lifecycle manage Doryx® into new dosages and formulations
- Other markets being assessed to expand Doryx® globally



Other products



- New Astrix® formulations under development to expand the product offering to patients
- New business development resource appointed to expand the contract manufacturing client base
- New product opportunities under review
 - Specialised generics for the US market
 - ICEs incorporating Mayne Pharma's proprietary drug delivery technology
- Reviewing new product opportunities for acquisition / in-licensing



Trading update

- Our year to date performance is up on last year for both sales and EBITDA
- Company expects 1H12 EBITDA to be up on last year
- Business now debt free
- US\$5m 3-year interest only bill facility negotiated, but not drawn
- Cash on hand (31/10/11) \$5.0m
 - Net cash up \$1.5m from 30 June 2011
 - Cash rebuild expected in FY12



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