



# Mayne Pharma Group Limited (ACN 115 832 963) Half Year Results Presentation 2011 25 February 2011





# **Highlights of the last six months**

- EU registration filed for SUBACAP®
- Successful US-based Phase II trial for SUBACAP®
- Change of company name to Mayne Pharma Group Limited
- New Chairman and CFO appointed
- Maiden dividend paid and special dividend declared
- New Doryx® formulations



## **Executive Summary**

- Strengthened A\$ and a delay in the approval of new Doryx® formulations has resulted in earnings not meeting Company expectations for the half
- Australian proprietary products division sales were up following acquisition of the marketing and distribution rights from Hospira in February 2010
- US\$10M debt reduced to US\$3.75M at end of January
- Special fully franked dividend of 1.0cps
- Continued legal action to protect Doryx® patent
- Seeking regulatory approval in EU for SUBACAP® in 2011 and clarity around US clinical development path from the FDA in the 2<sup>nd</sup> quarter of calendar 2011



## **Consolidated results for the half-year ended 31/12/10**

- Total revenue \$26.9m
- Gross profit \$12.2m
- EBITDA \$5.1m
- EBITDA margin 18.9%
- NPAT \$1.1m
- EPS 0.76cps
- Net operating cash flow before tax of \$3.7m
- Cash on hand \$13.4m
- Net cash (cash less debt) of \$8.5m
- Special dividend declared 1.0cps





## H11 Earnings comparison

¢ milliono	H11	H10	Last
\$ millions	Reported	Reported	12 months
Total revenue	26.9	9.3	54.3
Gross profit	12.2	5.2	24.6
EBITDA	5.1	(0.4)	14.0
Depreciation	(0.9)	(0.3)	(1.9)
EBITA	4.2	(0.7)	12.1
Amortisation	(3.1)	0.0	(8.6)
EBIT	1.1	(0.7)	3.5
Net interest	(0.8)	(0.4)	
Тах	0.8	(1.1)	
NPAT	1.1	(2.2)	
EPS (cents per share)	0.8	(2.1)	
EBITDA margin	18.9%	(4.4%)	25.8%



## **Key features of the results**

- Stronger AUD resulted in a net loss from foreign exchange of \$0.8m for the half
- \$1.7m margin shortfall from the agreed delay in Warner Chilcott orders for Doryx<sup>®</sup> tablets
- Notional interest charge of \$0.9m for the earn-out liability
- Savings in outward distribution costs and trading expenses against budget (\$0.4m or 22%)
- EU replicate study for SUBACAP® of \$0.6m to support commercialisation of the drug (\$1.1m in F11)





## **Balance Sheet Position**

\$ millions	H11	F10	H10	Change
Cash	13.4	19.7	14.6	(32.0%)
Inventory & receivables	14.0	12.5	11.3	11.8%
PP&E	21.3	21.0	19.3	1.3%
Intangibles	11.2	14.2	13.3	(21.0%)
Other	3.9	3.8	2.1	3.6%
Total assets	63.8	71.2	60.6	(10.4%)
Interest bearing debt	4.9	8.6	10.9	(43.3%)
Earn out liability	21.8	21.0	21.6	3.9%
Total liabilities	39.3	45.6	41.3	(13.8%)
Equity	24.5	25.5	19.4	(4.0%)
Net debt (debt less cash)	(8.5)	(11.1)	(3.7)	(23.2%)
Debt / Debt + Equity	16.6%	25.2%	36.0%	





### **Key features of the Balance Sheet movements**

- Cash reduction due to the payment of the maiden dividend (\$3.0m), reduction in the US\$ NAB loan (\$2.7m) and tax payments (\$2.9m)
- Increase in receivables from June due largely to the timing of a payment by Warner Chilcott (received in January 2011)
- Reduction in intangibles reflects aggressive amortisation schedule as foreshadowed at the end of FY10
- Debt reduced to less than half of the 31 December 2009 level
- Earn-out liability increased due to the notional (non-cash) interest charge reflecting the unwind of the discount (\$0.9m)





## **Cash flow**

\$ millions	H11
EBIT - reported	1.1
Amortisation / depreciation	4.0
Change in working capital	(1.4)
Net interest paid	(0.0)
Tax paid	(2.9)
Net operating cash flow	0.8
Capex	(1.1)
Acquisitions	0.0
Repayment of borrowings	(2.7)
Net proceeds from issue of shares	0.8
Dividends paid	(3.0)
Net cash flow	(5.2)
FX impact on cash	(1.1)
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Cash on hand at 30 June 2010	19.7
Cash on hand at 31 December 2011	13.4



# **Doryx**®

- Doryx<sup>®</sup> our key proprietary product representing ~50% of revenue
- Doryx® revenue impacted by
  - the stronger than expected AUD: forecast rate AUD/USD: 90c vs average actual settled rate of AUD/USD: 94c
  - delay in FDA approval of new formulations led to agreed deferral of orders with Warner Chilcott
- Vigorously defending patent which underpins marketing exclusivity for Doryx® in the US







## **Astrix**®

- Astrix® number 1 prescribed low dose aspirin in Australia representing 17% of group sales
- Astrix® sales and margins increased following acquisition of marketing and distribution rights from Hospira
- New consumer focused website <u>www.astrixaspirin.com.au</u> launched
- Partnership with HealthOne to promote Astrix<sup>®</sup> brand of products in pharmacies in Australia

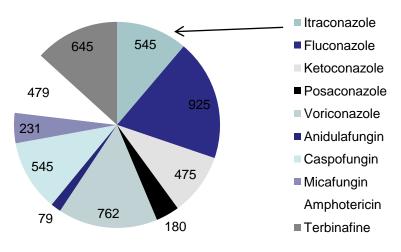




## **SUBACAP**®

- Super-bioavailable Itraconazole
- Patent protected
- EU registration filed Dec 2010
- Successful US based Phase II trial results in Nov 2010
- EU approval expected by end calendar 2011
- FDA meeting in 2<sup>nd</sup> quarter 2011 to discuss trial results and determine US regulatory path
- Reviewing potential licensing partners around the world





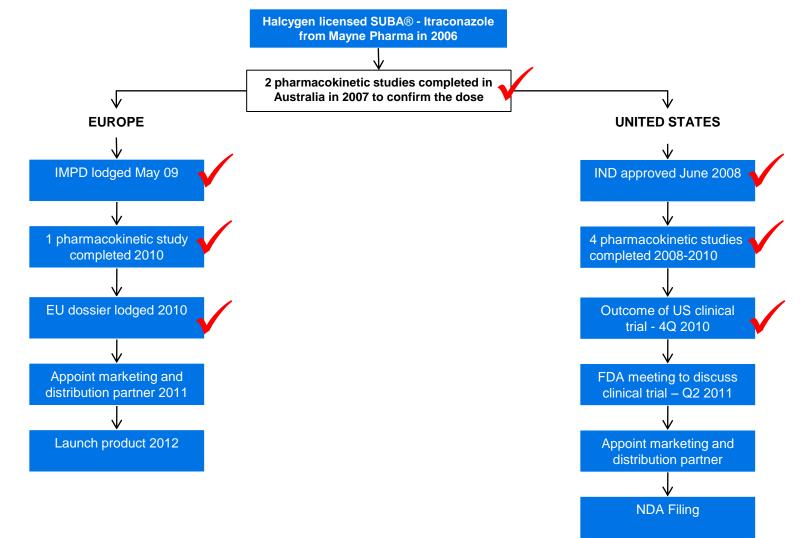
#### Total Value US\$4.87 billion Itraconazole US\$545 million

Source: Thomson Reuters June 2010





## **Clinical Development Path - SUBACAP®**





# Outlook

- The Company is in the process of transitioning into new improved Doryx<sup>®</sup> formulations
  - In view of the regulatory uncertainty surrounding FDA approval and the strategic decision to allow our major partner Warner Chilcott to delay orders, the previous guidance of EBITDA not less than \$18.2M is no longer appropriate
  - Normalisation of Doryx® supply is expected once FDA approval granted
  - The longer term position may improve given the possibility of price increases being implemented
- The Directors remain confident in the resilience and sustainability of our business model with our strong product portfolio and pipeline, particularly given the recent filing of SUBACAP® for registration in EU and ongoing discussions with potential marketing and distribution partners



#### **Dividend & debt repayment**

- After careful consideration of the outlook for the Company, the Board of Mayne Pharma has declared a special fully franked dividend of 1.0cps
  - Record date: 9<sup>th</sup> March 2011
  - Payable: 25<sup>th</sup> March 2011
- US\$ debt to be completely paid down in 2011





# **H11 Milestones**

Achieved

- ✓ SUBACAP® dossier lodged
- ✓ Successful Phase II trial of SUBACAP® in US
- ✓ Settlement with Heritage
- ✓ Special dividend

Ongoing

- Appointment of marketing and distribution partner for SUBACAP®
- Regulatory approval of SUBACAP® in EU and US
- Clarity around Doryx<sup>®</sup> lifecycle management
- Resolution of Doryx<sup>®</sup> patent litigation
- In licence/acquire/develop new products





# **Definitions and glossary of terms**

- IND Investigational New Drug Application
- IMPD Investigational Medical Product Dossier
- MHRA Medicines and Healthcare Products Regulatory Agency (UK)
- Pharmacokinetic study are performed to examine the absorption, distribution, metabolism and excretion of a drug under investigation in healthy volunteers
- Clinical studies are conducted in patients to determine safety and efficacy