



# Mayne Pharma Group Limited

FY13 Results Presentation  
27 August 2013

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# Disclaimer

- The information provided is general in nature and is in summary form only. It is not complete and should be read in conjunction with the company's Appendix 4E and market disclosures. This material is not intended to be relied upon as advice to investors or potential investors.

## Non-IFRS information

- Other than as indicated, the financial information contained in this document is directly extracted or calculated from the Appendix 4E. Throughout this document some non-IFRS financial information is stated excluding certain specified expenses. Results excluding such expenses are considered by the Directors to be a better basis for comparison from period to period as well as being more comparable with future performance
- Earnings before interest, tax, depreciation and amortisation (EBITDA) is considered by Directors to be the primary measure of earnings considered by management in operating the business and assessing performance
- The non-IFRS financial information has been reviewed by the Group's auditors

## Forward looking statements

- This presentation contains forward-looking statements that involve subjective judgement and analysis and are subject to significant uncertainties, risks and contingencies, many of which are outside the control of, and are unknown to the Company. No representation, warranty or assurance (express or implied) is given or made in relation to any forward looking statement by any person (including the Company). Actual future events may vary materially from the forward looking statement and the assumptions on which the forward looking statements are based. Given these uncertainties, readers are cautioned not to place undue reliance on such forward looking statements. The factors that may affect the Company's future performance include, among others: changes in economic conditions and changes in the legal and regulatory regimes in which the Company operates, changes in behaviour of major customers, suppliers and competitors.

# Executive summary

- Transformational period following the Metrics, Kapanol<sup>®</sup> and Libertas<sup>(1)</sup> acquisitions which have diversified earnings streams across products, technologies and geographies
- Exceeded or in-line with FY13 guidance announced at the time of the Metrics acquisition
- Despite the reduction in US Doryx<sup>®</sup> sales following generic competition, sales and profit growth was delivered over the year (excluding certain specified expenses):
  - Revenue of \$83.4m, up 60.8%.
  - Gross margin \$39.0m, up 72.9%.
  - Underlying EBITDA of \$18.4, up 61.2%.
- Reported EBITDA of \$9.3m and NPAT of (\$2.8m) includes \$4.4m of acquisition costs and a \$4.4m non-cash charge due to change in valuation of the Hospira earn-out liability
- Strong R&D Investment of \$10.9m, up 170% reflecting commitment to expand product portfolio & US acquisition:
  - 7 products pending at US FDA and 13 products pending at TGA
  - SUBACAP<sup>®</sup> approved in Europe and Doryx<sup>®</sup> 200mg strength tablet approved by FDA
- Solid financial position following recent capital raisings and strength of underlying operating performance:
  - Cash \$20.1m, up 73.6%
  - Interest bearing debt of \$46.7m (with substantial headroom under covenants)
- FY14 expected to benefit from growth in the doxycycline franchise, further expansion of the US generic portfolio, Kapanol<sup>®</sup> and sales and milestone payments from SUBACAP<sup>®</sup>

## FY13 comparison to guidance

	Guidance	Actual	
Revenue	\$69–82m	\$83m	Above guidance
– Mayne Pharma	\$38–45m	\$44m	In guidance
– Metrics	\$31–37m	\$39m	Above guidance
EBITDA <sup>(1)</sup>	\$16.1–18.7m	\$18.4m	In guidance
– Mayne Pharma	\$4.5–5.1m	\$5.2m	Above guidance
– Metrics	\$11.6–13.6m	\$13.2m	In guidance
NPAT <sup>(1)</sup>	\$4.3–5.2m	\$6.2m	Above guidance
Adjusted NPAT <sup>(1)(2)</sup>	\$8.1– 9.8m	\$9.6m	In guidance

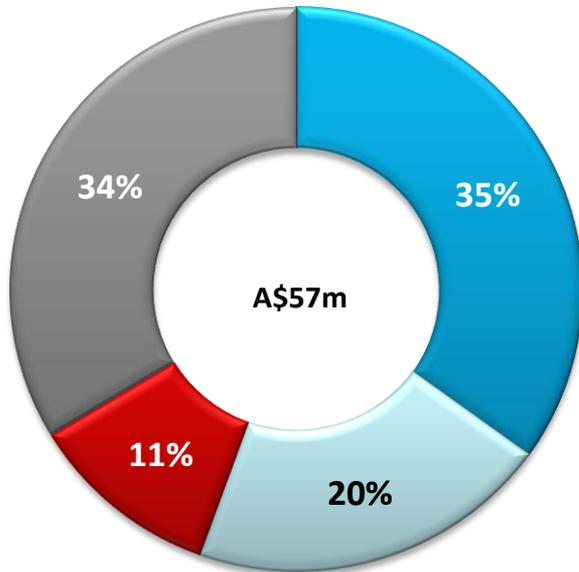
(1) Excludes \$4.4m of acquisition costs, \$4.4m for the non-cash change in the fair value of the earn-out liability associated with the Mayne Pharma International Pty Ltd (MPI) acquisition in November 2009 and \$0.2m arising from the revaluation of director's options as a result of the impact of the rights issue made as part of the funding for the acquisition.

(2) Excludes non-cash amortisation of intangibles after tax (\$2.4m) and notional non-cash interest expense (\$0.7m), representing the charge for the unwinding of the discount on the Hospira earn-out and non-cash LTI charge for Metrics senior management option plan (\$0.2m)

# Group sales breakdown

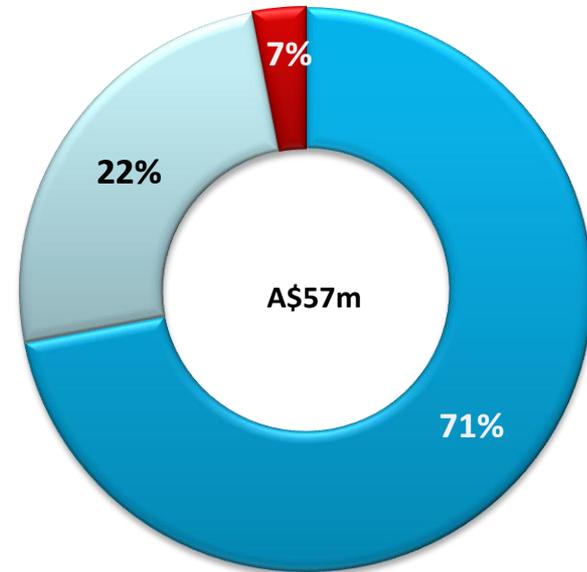
Diversified product revenue mix with increasing exposure to attractive US pharma market

2H13 Sales revenue by segment<sup>(1)</sup>



- US Generic Products
- Metrics Contract Services
- MPA
- MP Global

2H13 Sales revenue by region



- USA
- Australia
- Rest of World

(1) Pre inter-segment elimination and adjustment revenues and excludes other revenue

# US Generic Products (USGP)

- USGP segment manufactures and distributes generic pharmaceutical products in the US
- Sales were A\$25.2m and gross profit A\$15.8m for the 7.5 month period under Mayne Pharma ownership
- Over the 12 months to 30 June 2013, USGP sales were US\$40.3m, up 40% on pcp driven by the launch of oxycodone capsules and growth in the existing product portfolio
- 5 ANDAs have been filed in 2H13:
  - the Company now has 7 products currently pending at the FDA, targeting markets >US\$400m in sales (IMS Health)

## Outlook

- Revenue growth from recent acquisitions (Metrics & Libertas) and new product launches:
  - Doxycycline Hyclate Delayed-Release 75mg and 100mg tablets launched July 2013 – US\$24m market size
  - Erythromycin Delayed-Release 250mg capsules launched in August 2013 – US\$4m market size

## USGP sales by distribution channel

12 months to 30 June 2013



■ Direct
 ■ Exclusive partnerships

Number of ANDA products	14 Nov 12 <sup>(2)</sup>	Today
FDA approved – 3 <sup>rd</sup> party distribution	6	6
FDA approved – distributed directly <sup>1</sup>	2	12
FDA approved – total	8	18
FDA filed	2	7

(1) Includes 6 ANDAs from Libertas acquisition (acquired 2 July 2013), plus Doxycycline Hyclate DR tablets, Erythromycin DR capsules, Nystatin topical powder, Oxycodone HCL capsules, Oxy-APAP unit dose tablets and Oxycodone HCL unit dose tablets  
 (2) Date of Metrics acquisition



# Metrics Contract Services

- Metrics Contract Services provides contract pharmaceutical development services to third party customers principally in the US
- Sales were A\$14.8m and gross profit was A\$6.4m for the 7.5 month period under Mayne Pharma ownership
- Over the 12 months to 30 June 2013, Metrics Contract Services revenue was US\$24.5m up 2% on pcp
- Key enabler of US platform providing capability and know-how for US Generic Products business:
  - Provided analytical services for Mayne Pharma's ER pain management product
- Over 100 customers serviced in FY13
- Written quotes increased 6% over the 12 months to 30 June 13
- 55% of quotes were successfully closed over this period, in line with historical conversion rates
- Recently strengthened management – recruited VP, National Sales Manager of Contract Services

## Outlook

- Focused on optimising commercial operations to support further growth in this segment

# Mayne Pharma Australia (MPA)

## Highlights

- MPA sales were \$11.0m, up 11.9% on pcp following the acquisition of the Kapanol® rights in Australia from GSK on 1 February 2013
- Gross profit was \$5.0m up \$1.9m or 63% on pcp with the addition of Kapanol® and improved pricing of other products
- Other highlights include:
  - Completed recruitment of a national sales force to promote Kapanol®
  - Filed 9 products with the TGA (Total now filed: 13) driven primarily by the Intas partnership for injectable products
  - Percutane® launched during the year
  - Astrix® capsules ranged in 800 Woolworths stores

\$million	Jun 12	Jun 13	Change %
Sales revenue	9.8	11.0	11.9%
Gross profit	3.1	5.0	63.0%
Gross profit %	31.4%	45.7%	
No. of approved products	5	8	
No. of TGA filed products	0	9	

## Outlook

- Going forward, expect to see growth in pain and OTC portfolio with the addition of sales from the injectables portfolio in 2014
- Pipeline developments:
  - SUBACAP® filed with the TGA in March 2013
  - Licener, a new natural plant-based head lice treatment, has been added to the OTC portfolio. Head lice market valued at \$22m and growing 8% per annum
  - Expected approval of the filed injectable products in 2014

# Mayne Pharma Global (MP Global)

## Highlights

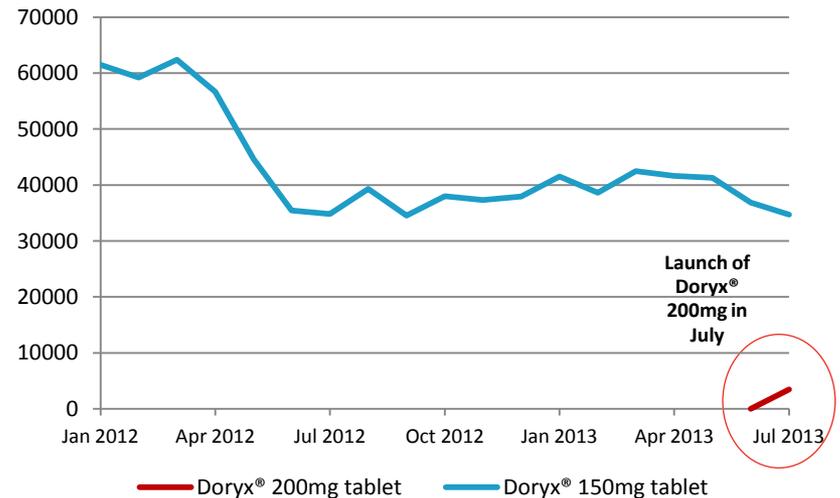
- MP Global sales were \$33.4m, down 20.7% on PCP reflecting the pipeline destocking of Doryx® in the first half following the launch of a competing generic
- Strong rebound in performance of MP Global in 2H13
  - Doryx® 150mg tablet has continued to maintain more than 60% market share following generic competition
- As previously announced, Doryx® 200mg tablet was approved by the FDA in April 2013 and launched in July 2013
  - 200mg Doryx® tablet has 3 years of market exclusivity
- SUBACAP® approved in several European countries

## Outlook

- Growth in FY14 expected from the launch of SUBACAP® in Europe, milestone payments from partners and a stronger performance of the doxycycline franchise in the US:
  - SUBACAP® to launch in the UK and Spain in FY14 and is expected to launch in FY15 in Italy and Portugal following completion of the 'repeat use' procedure

\$million	Jun 12	Jun 13	Change %
Sales revenue	42.1	33.4	-20.7%
Gross profit	19.5	12.2	-37.4%
Gross profit %	46.3%	36.6%	

Warner Chilcott Doryx® monthly TRx prescription volume



Increasing investment in R&D in FY14 of >\$15m to accelerate growth in new products

US



- 20 generic products under development targeting US markets with annual sales greater than US\$3bn<sup>1</sup>:
  - 7 generic products filed with the FDA targeting US markets with annual sales of greater than US\$400m<sup>1</sup>
- FDA approval timelines for ANDAs have stretched under GDUFA, however expect timelines to improve over the mid term

Australia



- 12 injectable products filed with the TGA targeting markets with annual sales of ~\$60m<sup>2</sup>
- Targeting TGA filing in 2014 of a US generic approved product with end market value of \$9m and no generic competition<sup>2</sup>

# Branded pipeline – SUBACAP<sup>®</sup> Itraconazole

	Regulatory status	Distribution Pathway	Expected launch	Market size <sup>1</sup>
 <b>Europe</b>	Approved in the UK, Spain, Sweden and Germany	ISDIN – Spain, Italy, Portugal. Glenmark – UK Late stage discussions with other partners for additional EU markets	FY14 - UK & Spain. FY15 – Italy, Portugal and other markets subject to ‘repeat use’ procedure	US\$80m
 <b>Australia</b>	Filed with TGA	Mayne Pharma Australia	FY15	US\$4m
 <b>Korea</b>	Expected filing in 2014	Late stage discussions with partner	FY16 subject to approval by Korean FDA	US\$30m
 <b>US</b>	Pivotal PK studies underway Expected filing in 2014	Market evaluation commenced	FY15-FY16 depending on final regulatory pathway	US\$70m
 <b>Japan</b>	-	Detailed market evaluation complete	TBC.	US\$130m
 <b>Rest of world</b>	-	Entry strategies underway for key markets	TBC.	US\$180m

(1) IMS health, MAT December 2012

# Earnings comparison

Improved underlying profitability achieved in FY13

\$ millions	Year ending	Year ending	Change	
	30 Jun 13	30 Jun 12	\$m	%
<b>Sales revenue</b>	<b>83.4</b>	<b>51.9</b>	<b>31.5</b>	<b>60.8%</b>
<b>Gross margin</b>	<b>39.0</b>	<b>22.6</b>	<b>16.4</b>	<b>72.9%</b>
<i>Gross margin %</i>	<i>46.7%</i>	<i>43.5%</i>		
EBITDA (as per guidance)	18.4	11.5	6.9	61.2%
Adjustments <sup>(1)</sup>	(9.1)	2.8	(11.9)	nm
<b>Reported EBITDA</b>	<b>9.3</b>	<b>14.3</b>	<b>(5.0)</b>	<b>(34.5%)</b>
Depreciation	(3.7)	(1.8)	(1.9)	106.3%
Amortisation	(3.7)	(3.8)	0.1	(2.9%)
Net interest <sup>(2)</sup>	(2.6)	(0.9)	(1.8)	208.7%
Tax	(2.1)	(1.6)	(0.5)	33.9%
<b>Reported NPAT</b>	<b>(2.8)</b>	<b>6.2</b>	<b>(9.0)</b>	<b>nm</b>
Adjusted NPAT (as per guidance) <sup>(1)(3)</sup>	9.6	6.0	3.6	60.7%

- (1) Adjustments include \$4.4m of acquisition costs, \$4.4m non-cash change in the fair value of the earn-out liability and \$0.2m arising from the revaluation of directors options as a result of the impact of the rights issue made as part of the funding for the acquisition\
- (2) Includes finance expenses (\$2.3m), notional non-cash interest expense of (\$0.7m) less interest revenue (\$0.4m)
- (3) Excludes non-cash amortisation of intangibles after tax (\$2.4m) and notional non-cash interest expense (\$0.7m), representing the charge for the unwinding of the discount on the Hospira earn-out and non-cash LTI charge for Metrics senior management option plan (\$0.2m)

## Key features of the financial result

- Overall sales were up \$32m with Metrics contributing \$39m or 47% of total sales
  - Mayne Pharma (excluding Metrics) sales were down \$8m following the launch of a competing generic Doryx<sup>®</sup> product
- Gross profit margins were stronger at 47% up from 44% in the pcp driven by the inclusion of US Generic Products segment (GM: 63%)
- Underlying adjustments made to FY13 EBITDA include:
  - \$4.4m of acquisition costs associated with Metrics and Kapanol<sup>®</sup> acquisitions
  - \$4.4m non-cash charge from the change in the fair value of the earn-out liability associated with the MPI acquisition from Hospira in November 2009
  - \$0.2m arising from the revaluation of director's options as a result of the impact of the rights issue made as part of the funding for the Metrics acquisition
- Net interest includes \$0.7m notional non-cash interest expense representing the charge for the unwinding of the discount on the earn-out for the MPI acquisition

# Balance Sheet position

Balance Sheet comparison highlights the transformation of Mayne Pharma's Net Asset profile across FY13

\$ millions	As at	As at	Change	
	30/6/13 <sup>1</sup>	30/06/12	\$m	%
Cash <sup>(2)</sup>	20.1	11.6	8.5	74%
Inventory & receivables	38.2	11.1	27.2	245%
PP&E	55.0	22.2	32.8	148%
Intangibles	115.5	4.2	111.3	2653%
Other assets	4.5	1.1	3.4	296%
<b>Total assets</b>	<b>233.4</b>	<b>50.2</b>	<b>183.2</b>	<b>365%</b>
Interest bearing debt	46.7	-	46.7	Nm
Other financial liabilities	28.2	9.3	18.9	202%
Other liabilities	37.6	10.3	27.3	266%
<b>Equity</b>	<b>120.9</b>	<b>30.6</b>	<b>90.3</b>	<b>295%</b>
Net debt (bank debt less cash)	26.6	(11.6)	38.2	nm

(1) USD:AUD FX rate of 0.914 for translation of USD balances

(2) Includes restricted cash of \$1.2m

## Key features of the financial position

- Total cash increased \$8.5m over the period
- US\$44.5m loan facility for the acquisition of Metrics and US\$4m working capital facility in place
- Intangible assets of \$115.5m comprise:
  - \$46.8m of goodwill
  - \$18.0m of development costs
  - \$13.8m for Kapanol<sup>®</sup> marketing and distribution rights
  - \$36.4m in other intangibles including customer relationships/customer contracts and trade names
- Other financial liabilities increased by \$18.9m reflecting the:
  - \$11.4m earn-out associated with the Metrics acquisition to be paid September 2013
  - \$3.4m deferred payment associated with the Kapanol<sup>®</sup> acquisition to be paid February 2014
  - \$4.4m non-cash change in the fair value of the earn-out liability associated with the MPI acquisition
  - \$0.7m notional non-cash interest expense
  - \$1.3m payment in February 2013 representing the calendar 2012 installment of the MPI acquisition earn-out

## Cash flow

\$ millions	30 June 13	30 June 12
EBITDA – underlying	18.4	11.5
Working capital movements & other	(3.6)	1.1
Net operating cash flow pre-tax, interest and transaction costs	14.8	12.5
Net interest received	(1.6)	0.2
Transaction costs	(4.4)	-
Tax received / (paid)	(2.0)	0.8
<b>Net operating cash flow</b>	<b>6.8</b>	<b>13.4</b>
Capitalised R&D	(7.5)	-
Acquisitions	(113.6)	-
Capex	(3.2)	(2.5)
Net proceeds from borrowings	40.6	(2.3)
Net proceeds from issue of shares	85.6	-
Payment of earn-out liability instalment	(1.3)	( 2.9)
<b>Net cash flow</b>	<b>7.5</b>	<b>5.6</b>

- Operating cash flow (pre-tax, interest and transaction costs) was \$14.8m, up 19%
  - Operating cashflow was less than underlying EBITDA primarily due to the increase in working capital over the period
- During the period \$89.6m was raised from shareholders and \$41.7m was drawn down from borrowings for the Metrics and Kapanol® acquisitions
- The Company invested \$10.9m in R&D of which \$7.5m was capitalised or 69% in line with accounting standards

# Mayne Pharma Growth Strategy

## 1. US retail generics maximisation

## 2. Doxycycline franchise optimisation

## 3. SUBACAP® global commercialisation

## 4. Australian pain franchise expansion

## 5. Optimise and grow US contract services

### Key activities

- Portfolio expansion through organic development and bolt-on acquisitions

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- Build doxycycline generic portfolio
- Optimise Doryx® franchise

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- Participate in global itraconazole market with US, Japan, Europe and Korea as priority markets: US\$490m global market<sup>(1)</sup>

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- Broaden portfolio through in-licensing, internally supplied products (Metrics), organic growth of Kapanol®

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- Globalise customer base
- Leverage combined business expertise

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(1) IMS Health, MAT December 2012

# Outlook

**Future  
catalysts for  
value**

- SUBACAP<sup>®</sup> launch in Europe and Australia
- US portfolio expansion through increasing market penetration of existing products and growing product pipeline
- Partner and file SUBACAP<sup>®</sup> in the US, Korea and Japan
- Deliver on key milestones for R&D program globally
- Launch selected Metrics products in Australia
- Launch the injectable portfolio in Australia
- Targeted in-licensing of niche generic and specialty products for the Australian market
- Product and enterprise acquisitions with attractive growth characteristics and aligned with strategic objectives