

# **Mayne Pharma Group Limited**

FY14 Results Presentation 27 August 2014

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• 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 audited Financial Statements and market disclosures. This material is not intended to be relied upon as advice to investors or potential investors.

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- Other than as indicated, the financial information contained in this document is directly extracted or calculated from the audited Financial Statements. Throughout this document some non-IFRS financial information is stated excluding certain specified expenses.
   Results excluding such expenses are considered by the Directors to provide a meaningful basis for comparison from period to period.
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- The non-IFRS financial information has not been audited by the Group's auditors.

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#### **Glossary**

A glossary of industry terminology is contained in the 2014 Annual Report which can be accessed at <a href="www.maynepharma.com">www.maynepharma.com</a> and product descriptions are detailed at <a href="www.maynepharma.com/products">www.maynepharma.com/products</a>.



## **Key financials**

- Revenue of \$143.3m, up 72% on pcp
- Gross profit of \$75.1m, up 92% on pcp
- Gross profit margin grew from 46.7% to 52.4%
- Reported EBITDA of \$43.1m up 364% on pcp
- Underlying EBITDA<sup>1</sup> of \$40.4m up 120% on pcp
- NPAT at \$21.3m
- Net operating cashflow (pre R&D/transaction costs) of \$30.5m, up 108% on pcp
- Cash R&D investment at \$19.8m, up 82% on pcp



## **Operational highlights**

- Strong growth in revenue and gross profit across all segments
- Successful integration of Libertas and US product acquisitions
- Margin expansion from changing sales mix and increased sales of key branded products
- New products launched in the US, Australia and Spain
- FDA approval of Oxycodone HCl Oral Solution and TGA approval of Lozanoc™ and Doxorubicin HCl IV
- 17 products now pending at the FDA and 16 products pending at the TGA
  - 8 products filed with the FDA and 5 products filed with the TGA during FY14
  - In-licensed 12 products for the Australian market and Temozolomide for the US market
- Appointed licensing partners for Lozanoc™ in Spain, Italy, Portugal, Austria, China and South Korea
- Agreement finalised with HedgePath Pharmaceuticals to exploit SUBA™-Itraconazole in various cancer indications in the US
  - ROW rights to developed IP retained by Mayne Pharma
- Management team strengthened across the organisation



### Mayne Pharma's business segments

## Mayne Pharma International (MPI)

(formerly MPA & MP Global)

#### Develops, manufactures, markets and distributes branded and generic products globally (principally Australian-

manufactured product)

# Key current products and services

- Branded specialty
  - Doryx<sup>™</sup>, Eryc<sup>™</sup>, Kapanol<sup>™</sup>,
     Lozanoc<sup>™</sup>, Urocarb<sup>™</sup>
- Branded OTC/Pharmacy
  - Astrix<sup>™</sup>, Licener<sup>™</sup>, Magnoplasm<sup>™</sup>,
     Percutane<sup>™</sup>
- Generic
  - Doxycycline, Erythromycin, Aspirin, Doxorubicin, Ondansetron
- Commercial contract manufacturing

#### **US Products (USP)**

 Develops, manufactures, markets and distributes branded and generic products in the US (principally US-manufactured product)

# Metrics Contract Services (MCS)

 Provides contract pharmaceutical development services to 3rd parties globally

- Branded
  - ESGIC™, LORCET™, ZEBUTAL™
- Generic
  - Amiodarone, Bromfenac,
     Butalbital/APAP/Caffeine,
     Doxycycline Hyclate,
     Erythromycin,
     Hydrocodone/APAP, Liothyronine,
     Methamphetamine, Nystatin,
     Oxycodone, Oxycodone/APAP
- Analytical services
- Formulation development
- Clinical trial batch manufacture
- Potent and cytotoxic services
- Commercial contract manufacturing

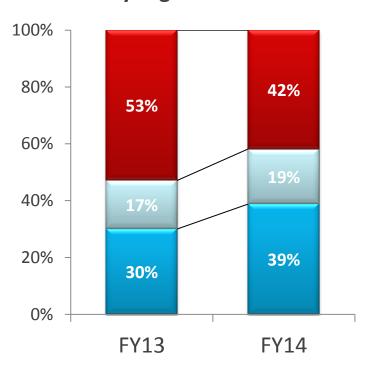
## Pipeline products

- 30+ products in pipeline
  - 16 products pending with the TGA
- 30+ products in pipeline
  - 17 products pending with the FDA
- n/a



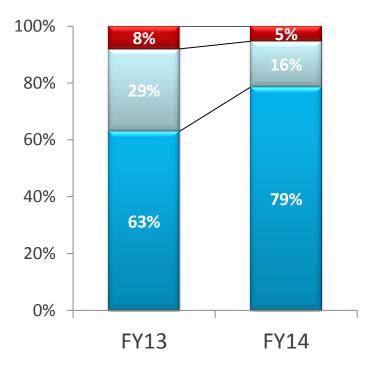
## **Group revenue breakdown**

### Revenue by segment<sup>(1)</sup>



- **■** US Products
- Metrics Contract Services
- MPI (formerly MPA and MP Global)

### Revenue by region<sup>(2)</sup>



- **USA**
- Australia
- Rest of World

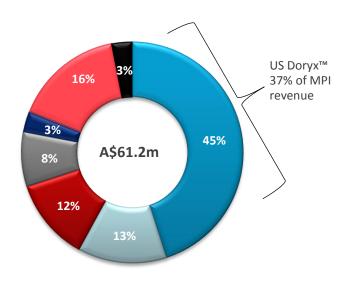
<sup>(1)</sup> Pre inter-segment elimination and adjustment revenues

<sup>(2)</sup> USA includes product manufactured by MPI for the US market



### MPI and USP revenue breakdown

#### MPI revenue breakdown

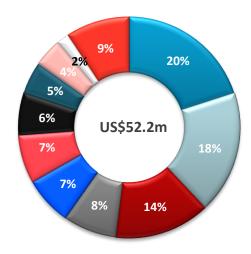


■ Aspirin■ Itraconazole

■ Contract manufacturing

- Doxycycline
- **■** Morphine
- **■** Erythromycin
- Other

### **USP** revenue breakdown



- Nystatin
- Oxycodone
- **■** Bromfenac
- Oxycodone/APAP
- ${\color{red} oxed{oldsymbol{ol}}}}}}}}}}}}}}}}}}}}}$
- Other

- **■** Liothyronine
- Butalbital/APAP/Caffeine
- **■** Doxycycline
- Amiodarone
- $\ \ \square$  Erythromycin

Increased product diversification has led to US Doryx™ decreasing from 40% of group revenue in FY12 to 16% in FY14



## **US Products (USP)**

#### **Highlights**

- New products launched in FY14 include:
  - Generic: Doxycycline Hyclate DR tablet,
     Erythromycin DR capsule, Hydrocodone/APAP
     tablet
  - Branded: ZEBUTAL™ capsules, ESGIC™ capsules and tablets and LORCET™ tablets
- Revenue uplift driven by Libertas acquisition, new product launches and growth of existing products including Nystatin and Oxycodone
- Gross profit margin decrease driven by inclusion of Libertas Pharma products which are third party sourced and reduced royalties from third party partnerships<sup>4</sup>

A\$million	FY13 <sup>1</sup>	FY14 <sup>2</sup>	Change FY14 v FY13
Revenue	25.2	56.9	125.5%
Gross Profit	15.8	32.0	102.7%
Gross Profit %	62.6%	56.3%	

#### **USGP** sales by distribution channel



<sup>(1)</sup> Includes Metrics from 14 November 2012

<sup>(2)</sup> Includes Libertas from 2 July 2014

<sup>(3)</sup> Includes 12 month contribution from Metrics

<sup>(4) 3</sup>rd party partnerships include the legacy products - Liothyronine distributed by Perrigo and Oxycodone, Bromfenac and Methamphetamine distributed by Mylan



## **Metrics Contract Services (MCS)**

#### **Highlights**

- New leadership and reinvigorated sales team delivering improved performance
  - MCS revenue was US\$26m up 6% on the 12 months to 30 June 2013
  - Introduced 17 new clients in FY14 up from 11 in prior 12 month period
  - Number of quotes signed up 30% on prior 12 month period
  - 65% of quotes were successfully closed in FY14 (56% in prior period)
  - Strong order book for 1HFY15
- Investment in new equipment and facilities to offer additional formulation and analytical services to clients
- Rebranding of the segment to Metrics Contract Services with the distinctive red dot logo, demonstrating it is an integrated member of the Mayne Pharma family

A\$million	FY13 <sup>1</sup>	FY14	Change FY14 v FY13
Revenue	14.8	28.4	92.1%
Gross Profit	6.4	13.0	101.2%
Gross Profit %	43.6%	45.6%	





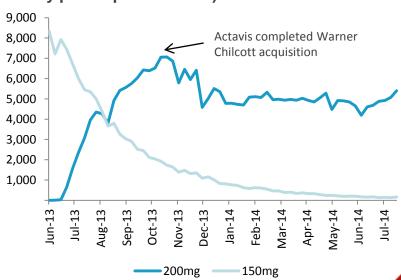
# Mayne Pharma International (MPI) (formerly MPA and MP Global)

#### **Highlights**

- Strong rebound in the performance of MPI driven by Doryx™ 200mg, licensing fee income and the additional contribution from Kapanol™
  - Doryx<sup>™</sup> 200mg now represents 97% of branded Doryx<sup>™</sup> scrips with volumes tracking ~5,000 scrips/week
  - 2HFY14 sales of US Doryx<sup>™</sup> down 24% on 1HFY14
- First commercial sales of Lozanoc<sup>™</sup> were made in Spain. ISDIN promoting Lozanoc<sup>™</sup> through its 200+ dermatology focused sales force
- Licensing fee income received from the outlicensing of SUBA<sup>™</sup>-Itraconazole to HedgePath Pharmaceuticals and Lozanoc<sup>™</sup> to a number of parties including Boryung and ISDIN

A\$million	FY13	FY14	Change FY14 v FY13
Revenue	44.4	61.2	37.8%
Gross Profit	17.2	31.3	81.7%
Gross Profit %	38.8%	51.2%	

## Warner Chilcott Doryx<sup>™</sup> tablet (Weekly prescription volume)





## **Earnings comparison**

	Year ending	Year ending	Cha	nge
\$ millions	30 Jun 14	30 Jun 13	\$m	%
Revenue	143.3	83.4	59.9	71.7%
Gross profit	75.1	39.0	36.1	92.5%
Gross profit %	52.4%	46.7%		
EBITDA	40.4	18.4	22.0	120.0%
Adjustments	2.7	(9.1)	11.8	NM
Reported EBITDA	43.1	9.3	33.8	363.7%
Depreciation / amortisation	(9.9)	(7.4)	(2.5)	33.8%
Net interest <sup>(1)</sup>	(5.2)	(2.6)	(2.6)	100.0%
Tax	(6.7)	(2.1)	(4.6)	219.0%
Reported NPAT	21.3	(2.8)	24.1	NM



### **Notable items**

- Revenue includes licensing fee income of \$4.9m which includes:
  - \$4.5m non-cash income from the out-licensing of SUBA™-Itraconazole to HedgePath Pharmaceuticals (HedgePath) in return for an equity stake of 41.5% in HedgePath; and
  - \$0.4m from the out-licensing of Lozanoc™ to a number of parties including Boryung and ISDIN
- Gross profit margins were stronger at 52% up from 47% in the pcp driven by a significant rebound in MPI margins (GM: 51% versus 39% in pcp)
- Underlying adjustments made to FY14 EBITDA include:
  - \$0.8m of acquisition costs associated with the Libertas, ZEBUTAL™, ESGIC™, LORCET™ and HedgePath transaction;
  - \$4.3m non-cash credit resulting from the decrease in the fair value of the Hospira earn-out liability
  - \$0.4m provision for the anti-trust action in the USA; and
  - \$0.3m non-cash expense arising from the revaluation of options as a result of the impact of the rights issue made as part of the funding for the Metrics, Inc. acquisition
- Prima facie tax was reduced by R&D concessions, restatement of deferred tax balances in the US and prior year overprovision



## **Balance Sheet position**

	As at	As at	Chan	ge
\$ millions	30/6/14	30/6/13	\$m	%
Cash	14.8	18.9	(4.1)	(21.7%)
Inventory	17.2	13.6	3.6	26.8%
Receivables	29.8	24.6	5.2	21.1%
PP&E	53.4	55.0	(1.6)	(3.0%)
Development expenditure	33.4	18.0	15.4	85.7%
Other intangibles & goodwill	107.7	97.5	10.2	10.5%
Other assets	9.5	5.7	3.8	66.7%
Total assets	265.8	233.4	32.4	13.9%
Interest-bearing debt	48.0	46.7	1.3	2.9%
Other financial liabilities	11.3	28.2	(16.9)	(60.1%)
Other liabilities	47.2	37.6	9.6	25.6%
Equity	159.3	120.9	38.4	31.8%
Net debt (bank debt less cash)	33.2	27.8	5.5	19.7%



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

- Intangible assets and goodwill increased by \$25.6m reflecting:
  - \$16.3m of development costs;
  - \$4.3m for acquisition of Libertas;
  - \$13.6m for marketing and distribution rights associated with ZEBUTAL™, ESGIC™ AND LORCET™;
  - \$4.9m of amortisation; and
  - \$3.6m from the effects of foreign currency translation
- Borrowings increased by \$1.3m
  - US\$47m outstanding loan for the acquisition of Metrics in November 2012
  - Term loan increased by US\$2.6m over the period following US\$8.5m drawdown to partly fund the Metrics earn-out, offset by US\$5.9m of loan repayments
- Other financial liabilities decreased by \$16.9m reflecting:
  - \$11.4m earn-out payment for the Metrics acquisition;
  - \$3.4m deferred payment associated with the Kapanol™ acquisition;
  - \$3.3m payment in February 2014 representing the calendar 2013 instalment of the Hospira earn-out;
  - \$4.3m non-cash credit reflecting the decrease in the Hospira earn-out liability;
  - \$4.5m of earn-outs recognised for the Libertas, ZEBUTAL™, ESGIC™ AND LORCET™ acquisitions; and
  - \$1.1m notional non-cash interest expense



## **Cash flow**

	Year ending	Year ending	Change
\$ millions	30 Jun 14	30 Jun 13 <sup>1</sup>	\$m
EBITDA - underlying	40.4	18.4	22.0
HedgePath equity investment (non-cash)	(4.5)	-	(4.5)
Working capital movements & other	(1.6)	(3.6)	2.0
Net operating cash flow before tax, interest and transaction costs	34.3	14.8	19.5
Net interest paid	(3.7)	(1.6)	(2.1)
Net tax paid	(3.7)	(2.0)	(1.7)
Transaction costs	(0.8)	(4.4)	3.6
Net operating cashflow	26.1	6.8	19.3
Capitalised R&D	(16.3)	(7.5)	(8.8)
Acquisitions	(15.6)	(113.6)	98.1
Capex	(4.2)	(3.2)	(1.0)
Net proceeds from borrowings & shares	19.9	126.2	(106.3)
Payment of earn-out liability instalment	(14.7)	(1.3)	(13.4)
Net cash flow	(4.8)	7.5	(12.3)



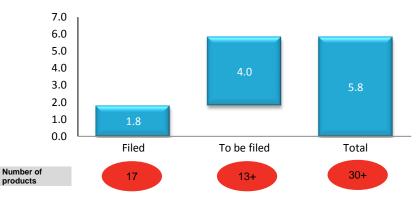
## Pipeline update

>30 filings under review today with the FDA and TGA US addressable market<sup>1</sup> for FDA filed products increased from \$0.4bn to US\$1.8bn

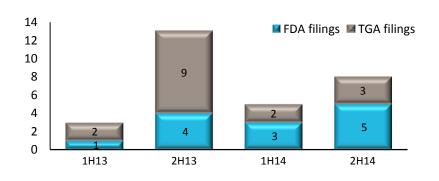
#### R&D cash investment (US\$m)



## US Pipeline statistics – IMS market size (US\$bn)<sup>2</sup> August 2014



#### **Product filings (number)**



## AU Pipeline statistics – IMS market size (A\$m)<sup>2</sup> August 2014



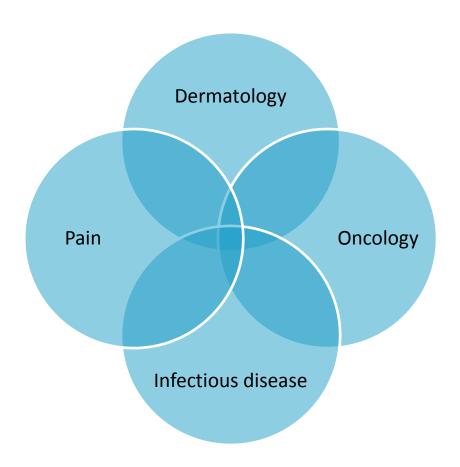
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(2) IMS Health MAT Jun 2014

<sup>1)</sup> Addressable market is defined as current annual sales of therapeutically and pharmaceutically substitutable products relevant to each pipeline product as defined by IMS Health data for the 12 months period ending 30 June 2014



### Specialty product and business development focus



#### **Expanding our specialty platform**

- Maximise value from Lozanoc™ anti-fungal application
- Expand global footprint through out-licensing key branded products
  - Kapanol™ rest of world rights acquired back from GSK
- Exploit repurposing of existing products in new therapeutic areas
  - SUBA™- Itraconazole in cancer
- Leverage and expand US and Australian commercial infrastructure to exploit new specialty brand opportunities
- Continued development of new specialty products employing drug delivery technology
- New patents filed/approved that strengthen protection of key products e.g. Doryx<sup>™</sup>, Lozanoc<sup>™</sup>



### **Senior management recruits**

#### **Stefan Cross**

#### **President - Mayne Pharma USA**

- 20+ years of industry experience
- Previous experience includes Hospira, Mayne
   Pharma Limited and FH Faulding & Co.

#### **Chris Schneider**

#### **Executive VP - Generic Products**

- 25+ years of industry experience
- Previously founder of Libertas Pharmaceuticals and was at Glades Pharmaceuticals, part of GSK

#### **John Ross**

#### **Executive VP - Metrics Contract Services**

- 20+ years of industry experience
- Previous experience includes Tunnell Consulting and Contract Pharmaceuticals

#### Ilana Stancovski, PhD Chief Scientific Officer

- 20+ years of industry experience
- Previous experience includes Actavis, Intas and Pfizer

#### **Blake Cullen**

#### **VP - US Business Development**

- 20+ years of industry experience
- Previous experience includes Rhodes
   Pharma, Libertas Pharma, Paddock Labs and
   Prasco Labs

#### **Danny Dragovic**

#### **Director - Australian Business Development**

- 10+ years of industry experience
- Previously held global marketing and business development roles with Fresenius Kabi and Hospira

More than 100 years of diverse international pharma experience brought in to drive execution of growth strategy



## **Future catalysts for value**

#### **Growth strategy**

## US retail generics maximisation

- Approval and launch of filed FDA products
- Optimise market penetration of product portfolio
- Portfolio expansion through growing product pipeline
- Efficient and reliable product sourcing, manufacturing and supply

## Doxycycline franchise optimisation

- Leverage patent and data exclusivity
- Optimise market penetration of US product portfolio

#### **R&D** execution

- Portfolio selection that leverages drug delivery expertise in complex generics and specialty products
- Selective paragraph IV filings in the US
- Development of SUBA<sup>™</sup>-Itraconazole in cancer in alliance with HedgePath Pharmaceuticals

# Strategic acquisitions, licensing and partnerships

- Licensing niche generic or specialty products in Australia and US
- Products such as Lozanoc™ through licensing arrangements in key markets to broaden global footprint
- Product and enterprise acquisitions with strong growth potential, complementary assets and technologies
- Build an injectable and pain portfolio in Australia



### **Outlook**

#### **US Products**

- US Generic market grew 15% in FY14 to US\$62bn¹ driven by strong underlying fundamentals
- Consolidation of retail customer base is creating more competitive market dynamics
- Further revenue growth expected from recent product acquisitions (ESGIC™, LORCET™ and ZEBUTAL™), further growth in the generic Doxycycline franchise and new product launches including Oxycodone Hydrochloride Oral Solution which occurred this month
- The Company remains confident that the FDA will approve some of the 17 filed products in FY15

## **Metrics Contract Services**

- US Contract Service market growing around 5% per annum
- Key performance indicators such as the number quotes written and signed as well as committed business pipeline trending strongly indicating a positive outlook for MCS in the coming year

## Mayne Pharma International

- MPI revenue expected to be down in FY15 as a result of reduced branded US Doryx<sup>™</sup> sales reflecting the recent lower underlying prescription volumes and anticipated resultant destocking at Actavis and lower licensing fee income
- Excluding US Doryx and licensing fees, MPI sales and gross profit is expected to be up driven by Kapanol™, Lozanoc™ and the launch of an injectable portfolio

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