



# Mayne Pharma Group Limited

## FY12 Results Presentation

21st August 2012

- Double digit revenue growth across the portfolio
- Strong results delivered
  - EBITDA \$14.3m, up 81%; NPAT \$6.2m, up 265%
  - Underlying EBITDA \$11.5m, up 25%
- Cost savings from operational restructure improved margins and earnings growth
- Robust net operating cash flow
- Doryx<sup>®</sup> sales not following typical generic substitution curve
- SUBACAP<sup>®</sup> on track for European approval in FY13
- Commencement of 2 new R&D projects targeting US market opportunity of US\$1.4bn
- Management team strengthened with the appointment of a new CEO and Sales and Marketing Director

| \$ millions                | FY12        | FY11       | Change     |              |
|----------------------------|-------------|------------|------------|--------------|
|                            |             |            | \$m        | %            |
| Sales revenue              | 51.9        | 47.0       | 4.9        | 10.4         |
| Gross margin               | 22.6        | 20.1       | 2.5        | 12.4         |
| <b>EBITDA – Underlying</b> | <b>11.5</b> | <b>9.2</b> | <b>2.3</b> | <b>25.0</b>  |
| Adjustments                | 2.8         | (1.3)      | 4.1        | Nm           |
| <b>EBITDA</b>              | <b>14.3</b> | <b>7.9</b> | <b>6.4</b> | <b>81.0</b>  |
| Depreciation               | (1.8)       | (1.8)      | 0.0        | 0.0          |
| EBITA                      | <b>12.5</b> | <b>6.1</b> | <b>6.4</b> | <b>104.9</b> |
| Amortisation               | (3.8)       | (6.1)      | 2.3        | (37.7)       |
| PBIT                       | <b>8.7</b>  | <b>0.0</b> | <b>8.7</b> | <b>Nm</b>    |
| Net interest <sup>1</sup>  | (0.9)       | (1.5)      | 0.6        | (40.0)       |
| Tax                        | (1.6)       | 3.2        | (4.8)      | (150.0)      |
| NPAT                       | <b>6.2</b>  | <b>1.7</b> | <b>4.5</b> | <b>264.7</b> |
| Basic EPS (cps)            | 4.1         | 1.1        | 3.0        | 272.7        |
| EBITDA margin - underlying | 22.2%       | 19.6%      | Δ259bps    |              |

1. Includes notional non-cash interest expense arising from the unwinding of the earn-out discount

# Key features of the financial result

- Expanded sales across all segments of the portfolio
  - US Doryx® sales up 10.7% despite strong AUD and reduced shipments following the launch of a generic
  - Sales of non-US Doryx® products represented 61% of the portfolio, up 10.5%
- Average AUD/USD rate settled in FY12 increased 6% on pcp impacting earnings by \$1.3m on a constant currency basis
- EBITDA margins improved following operational restructure and reduced R&D expenses as a result of reduced clinical and development work on SUBACAP® and Doryx®
- Adjustments to FY12 EBITDA
  - \$3.9m credit in results representing a reduction in the earn-out valuation due to reduced payments forecast to Hospira for the acquisition of Mayne Pharma International Pty Ltd
  - \$0.9m of termination payments to the former CEO and other senior management
  - \$0.2m impairment to intangible assets
- \$1.0m notional non-cash interest charge, representing the unwind of the discount on the earn-out

| \$ millions               | As at<br>30/06/12 | As at<br>30/6/11 | Change     |             |
|---------------------------|-------------------|------------------|------------|-------------|
|                           |                   |                  | \$m        | %           |
| Cash                      | 11.6              | 5.8              | 5.8        | 100.0       |
| Inventory & receivables   | 11.1              | 12.1             | (1.0)      | (8.3)       |
| PP&E                      | 22.2              | 21.5             | 0.7        | 3.2         |
| Intangibles               | 4.2               | 8.2              | (4.0)      | (48.8)      |
| Other assets              | 4.8               | 6.1              | (1.3)      | (21.3)      |
| <b>Total assets</b>       | <b>53.9</b>       | <b>53.7</b>      | <b>0.2</b> | <b>0.4</b>  |
| Interest bearing debt     | -                 | 2.3              | (2.3)      | (100.0)     |
| Earn-out liability        | 9.3               | 15.1             | (5.8)      | (38.4)      |
| Total liabilities         | 23.3              | 29.5             | (6.2)      | (21.0)      |
| <b>Equity</b>             | <b>30.6</b>       | <b>24.2</b>      | <b>6.4</b> | <b>26.4</b> |
| Net cash (cash less debt) | 11.6              | 3.5              | 8.1        | 231.4       |

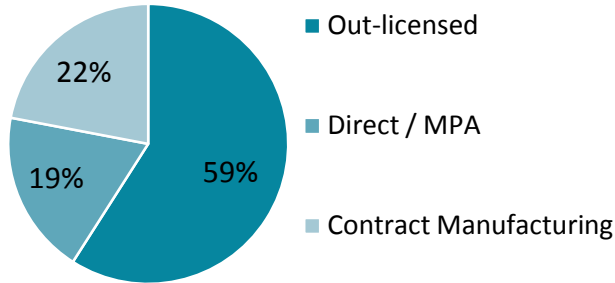
# Key features of the financial position

- Solid operating cash flow of \$13.4m drove net cash increase of \$8.1m
- US\$10m loan facility for the acquisition of Mayne Pharma International Pty Ltd in November 2009 repaid
- Earn-out reduced by \$5.8m reflecting
  - \$2.9m payment of earn-out instalment;
  - \$3.9m reduction in valuation; and
  - \$1.0m increase for notional non-cash interest charge reflecting unwind of the discount
- Working capital reduction due to tight control of receivables during the period
- \$2.5m of capital expenditure includes itraconazole spray dryer and aspirin tablet press
- \$4.0m reduction in intangibles reflects aggressive amortisation schedule

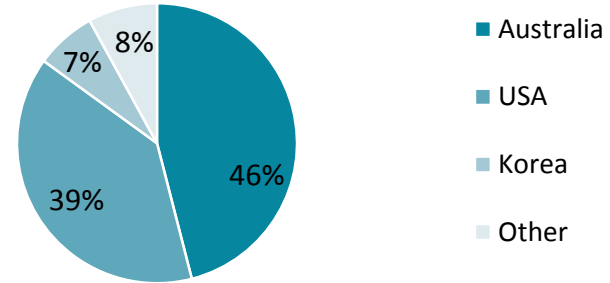
| \$ millions                              | FY12        | FY11          |
|--|-------------|---------------|
| <b>PBIT</b>                              | <b>8.7</b>  | <b>0.0</b>    |
| Amortisation / depreciation              | 5.6         | 7.9           |
| Reduction in earn-out liability          | (3.9)       | -             |
| Net interest received                    | 0.2         | 0.0           |
| Tax received / (paid)                    | 0.8         | (2.9)         |
| Other                                    | 2.0         | (0.9)         |
| <b>Net operating cash flow</b>           | <b>13.4</b> | <b>4.1</b>    |
| Capex                                    | (2.5)       | (2.1)         |
| Repayment of borrowings                  | (2.3)       | (5.1)         |
| Payment of earn-out liability instalment | ( 2.9)      | (6.6)         |
| Net proceeds from issue of shares        | -           | 1.5           |
| Dividends paid                           | -           | (4.5)         |
| <b>Net cash flow</b>                     | <b>5.6</b>  | <b>(12.7)</b> |
| FX impact on cash balance                | 0.2         | (1.2)         |
| <b>Cash on hand</b>                      | <b>11.6</b> | <b>5.8</b>    |

# Group sales breakdown

## Channel sales



## Regional sales



### Change pcp

|                            |        |
|----------------------------|--------|
| Direct (MPA)               | +5.6%  |
| Out-licensed               | +13.0% |
| Out-licensed (excl. Doryx) | +17.8% |
| Contract manufacturing     | +9.0%  |

### Change pcp

|           |        |
|-----------|--------|
| Australia | +6.9%  |
| USA       | +10.7% |
| Korea     | +17.9% |
| Other     | +28.5% |

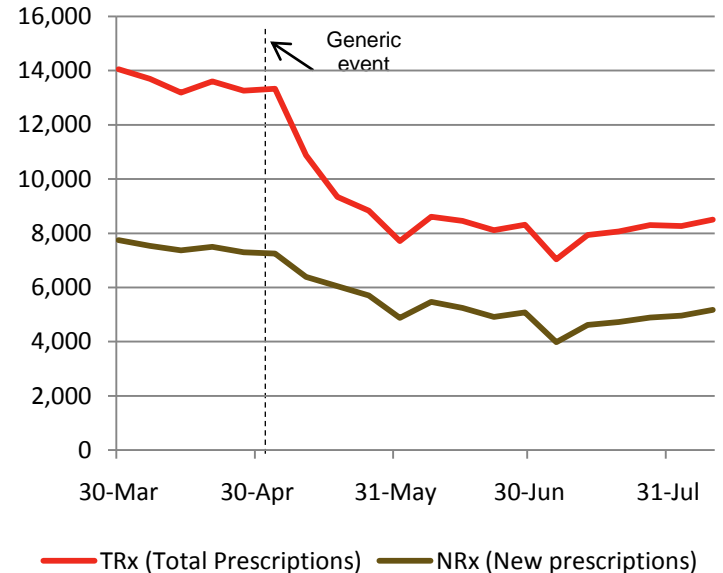


- Mayne Pharma Australia represents \$9.8m or 19% of sales and up 5.6% on pcp
- New pricing program implemented for key products in final quarter of FY12
- New aspirin tablet press validated and first shipments of Salisbury manufactured Astrix® and Mayne Pharma branded aspirin tablets commenced in July 2012
- Ongoing review of opportunities to in-license or acquire new products not currently available in Australia in niche generic and specialty product segments

- Out-licensed sales represent \$30.6m or 59% of total sales and were up 13.0% on pcp
- Out-licensed sales excluding Doryx® up 17.8% to \$10.2m
- Mayne's Korean partner, Boryung, continues to actively market Astrix® and grow sales at double digit levels
- Teva and Meda drove European sales of Eryc up \$0.5m or 94.3%
- Proprietary products to be rolled-out into additional markets
  - Existing products are marketed in only 10 countries today

- Mayne Pharma FY13 US Doryx sales are expected to be significantly below FY12 sales due to timing of generic launch and destocking of the pipeline in line with the new underlying demand profile
- US Doryx prescriptions not following typical generic substitution curve
  - Doryx® 150mg tablet prescriptions have fallen approx 35% since the entry of generic competition
  - Prescriptions have stabilised for 8 weeks over June/July
- Warner Chilcott maintaining its Doryx® national sales force and its customer loyalty card

**Warner Chilcott Doryx® 150 mg tablet (Weekly prescription volume)**



Source: Broker research

## Patent non-infringement

- Appeal on the non-infringement judgement on the Doryx® '161 patent has been filed with the US Court of Appeals

## Anti-trust

- In July 2012, Mylan filed an anti-trust suit against Warner Chilcott LLC and Mayne Pharma in the U.S. District Court
- Mylan alleges that the defendants have engaged in conduct that constrained generic competition for Doryx®
- The Company received notification of three further anti-trust suits from Rochester Drug Co-operative, Meijer Inc. and American Sales Company LLC
- Mayne Pharma does not foresee incurring any material financial liabilities in relation to these actions based on pre-existing contractual rights with Warner Chilcott and current legal advice

- Contract manufacturing of liquids and creams represents \$11.4m or 22% of sales and up 9.0% on pcp
- New product lines introduced by customers are continuing to drive this part of the business
- Recently renegotiated more than 50% of contract manufacturing volume for a further 3 years
- Mayne Pharma is actively exploring new contract manufacturing opportunities to utilise excess capacity in the factory

Current Tier 1 product candidate pool representing US\$5.8 billion in annual sales<sup>(1)</sup>

- R&D program focused on the development of generic and proprietary complex modified release oral products
- SUBACAP®
  - Improved formulation of itraconazole
  - Time to market < 1yr in Europe
- Extended release (ER) pain capsule
  - AB-rated ANDA<sup>(2)</sup>
  - Collaborative program with US drug delivery company
  - Preparing for pivotal biostudies
  - Expected file date 2013
- Extended release (ER) anti-hypertensive tablet
  - AB-rated ANDA<sup>(2)</sup>
  - pellet-in-a-tablet
  - Prototype formulation identified
  - Expected file date 2014

Under development

Identified projects (US ANDAs)

| Product            | Indication                        | Size of market <sup>(1)</sup> US\$m | Key patent expiry |
|--------------------|-----------------------------------|-------------------------------------|-------------------|
| SUBACAP®           | Fungal infection                  | 500                                 | MPG patent 2020   |
| ER capsule         | Pain                              | 270                                 | Expired           |
| ER tablet          | Hypertension                      | 1,100                               | Expired           |
| Film coated tablet | Antidepressant/ antischizophrenia | 1,000                               | 2017              |
| ER capsule         | Gastric reflux                    | 640                                 | Expired           |
| Capsule            | Alzheimer's                       | 600                                 | 2015              |
| Capsule            | Stroke reduction                  | 450                                 | 2017              |
| Capsule            | Crohns / IBS                      | 390                                 | 2015              |
| ER tablet          | Overactive bladder                | 250                                 | 2016              |
| ER capsule         | Hypertension                      | 250                                 | Expired           |
| ER capsule         | ADHD                              | 140                                 | 2020              |
| ER capsule         | Psychostimulant /ADHD             | 110                                 | Expired           |
| ER capsule         | Hypertension                      | 60                                  | Expired           |
| <b>Total</b>       |                                   | <b>5,760</b>                        |                   |

(1) IMS Health (ex-wholesaler) US sales MAT Dec 2011, except SUBACAP® which is the global (ex-wholesaler) sales MAT Dec 2011 of itraconazole

(2) Abbreviated new drug application

## SUBACAP<sup>®</sup> European approval on track for FY13

### Europe


- MHRA announced in June that SUBACAP<sup>®</sup> approvable in the UK
- Mayne Pharma submitting response to reactivate the Decentralised Procedure in Germany, Spain and Sweden
- Approval anticipated next 6 months

### USA

- Currently refining the proposed US regulatory pathway
  - US FDA Special Protocol Assessment completed for the design of the Phase III clinical trial in onychomycosis (nail infection)
  - Meeting with the FDA in November 2012 to discuss the argument presented to the MHRA (which may avoid the need for a Phase III trial)

### Australia

- Pre-submission meeting to apply for marketing approval of SUBACAP<sup>®</sup> with the Therapeutic Goods Administration (TGA) in 2013

- 
- Process commenced to secure marketing and distribution partner(s) for SUBACAP<sup>®</sup> in Europe and US
  - In discussions with several global and regional pharmaceutical organisations

## Milestones achieved

- SUBACAP® approvable in UK
- Debt paid down
- Appointment of Adelaide-based CEO and Sales and Marketing Director
- Commencement of two new R&D projects
- Renegotiated major contract customer for a further 3 years
- Manufacture of aspirin tablets in-house



## Future catalysts for value

- Regulatory approval of SUBACAP® in Europe and partner identification
- Optimal US regulatory pathway and partner identification for SUBACAP®
- Appointment of new international distribution partners for existing products
- Expand MP Australia portfolio with niche generic and specialty products
- Deliver on key milestones for broader R&D program

### Expected timing

*FY13*

*FY13*

*Ongoing*

*Ongoing*

*Ongoing*