



27 February 2013

## MAYNE PHARMA REPORTS INTERIM RESULT GUIDANCE ACHIEVED

Mayne Pharma Group Limited (Mayne Pharma; ASX: MYX) is pleased to release its consolidated results for the half-year ended 31 December 2012.

The Group recorded sales revenue of \$27.0m and a reported net loss after tax of \$2.5m, with acquisition costs of \$3.9m being a major non-recurring expense for the period. Reported earnings before interest, tax, depreciation and amortisation (EBITDA) was \$1.2m and underlying EBITDA (as defined below) was \$5.4m.

Net profit after tax (NPAT) excluding non-recurring items was \$1.6m which was above guidance, due mainly to the stronger than expected performance of Metrics, Inc. (Metrics) and a higher than expected capitalisation of development spend. Underlying EBITDA was slightly above the top end of guidance provided at the time of the Metrics acquisition, which was effective 14 November 2012. Refer below for further analysis of performance against guidance.

### Summary of results

| \$m  | 1H13         | 1H12        | Change on pcp |         |
|--|--------------|-------------|---------------|---------|
|  |              |             | \$m           | %       |
| <b>Sales revenue</b>                             | <b>27.0</b>  | <b>26.8</b> | 0.2           | 0.8     |
| <b>Gross margin</b>                              | <b>11.9</b>  | <b>12.2</b> | (0.3)         | (2.4)   |
| <i>EBITDA – underlying</i>                       | 5.4          | 6.3         | (0.9)         | (14.5)  |
| Adjustments <sup>1</sup>                         | (4.2)        | 2.5         | (6.7)         | (267.2) |
| <b>EBITDA</b>                                    | <b>1.2</b>   | <b>8.8</b>  | (7.6)         | (85.9)  |
| Depreciation / Amortisation                      | (2.1)        | (2.8)       | 0.7           | (25.9)  |
| <b>PBIT</b>                                      | <b>(0.9)</b> | <b>6.0</b>  | (6.9)         | (115.0) |
| Net interest <sup>2</sup>                        | (0.5)        | (0.6)       | 0.1           | (16.7)  |
| Income tax expense                               | (1.1)        | (1.5)       | 0.4           | (26.7)  |
| <b>NPAT</b>                                      | <b>(2.5)</b> | <b>3.9</b>  | (6.4)         | (165.6) |
| EPS (cps)  | (1.0)        | 2.6         | (3.6)         | (139.2) |
| Net operating cash flow before transaction costs | 4.2          | 4.1         | 0.1           | 2.4     |
| Cash at bank                                     | 30.4         | 11.6        | 18.8          | 162.0   |

- Underlying adjustments to EBITDA in 1H13 include \$3.9m of acquisition costs 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.
- Includes notional non-cash interest expense of \$0.4m, representing the charge for the unwinding of the discount on the earn-out for the Mayne Pharma International Pty Ltd acquisition in November 2009.

Mayne Pharma's CEO, Mr Scott Richards said "The 1H13 period was nothing less than transformational for Mayne Pharma following the changes made during the period to diversify our earnings streams across products, technologies and geographies. Following the diversification activities and investments in the management team, the Company is in a much more sustainable position with a larger portfolio of branded and generic products and a

pipeline with 17 products under development targeting the world's largest pharmaceutical market.”

Metrics contributed sales of \$8.2m and \$3.5m of EBITDA for the approximate six week period from the acquisition date, which was slightly ahead of the top end of guidance driven by a solid performance of the generic products division.

Mayne Pharma (excluding Metrics) contributed sales of \$18.8m and EBITDA of \$1.9m which was in the middle of the guidance range. Although Doryx® faced a challenging period with the launch of a competing product in the US, the performance of Mayne Pharma (excluding Metrics and Doryx®) was positive compared to prior comparable period (pcp) with a solid improvement in gross profit, up \$0.4m to \$4.4m.

### Performance against guidance

The table below compares the results for the period against the guidance provided to the ASX at the time of the Metrics acquisition.

|                                       | Guidance           | Actual        |                |
|---------------------------------------|--------------------|---------------|----------------|
| <b>Revenue</b>                        | <b>\$25–30m</b>    | <b>\$27m</b>  | In guidance    |
| - Mayne Pharma                        | \$19–22m           | \$19m         | In guidance    |
| - Metrics                             | \$6–8m             | \$8m          | In guidance    |
| <b>EBITDA<sup>(1)</sup></b>           | <b>\$4.2–5.2m</b>  | <b>\$5.4m</b> | Above guidance |
| - Mayne Pharma                        | \$1.8–2.0m         | \$1.9m        | In guidance    |
| - Metrics                             | \$2.4–3.2m         | \$3.5m        | Above guidance |
| <b>NPAT<sup>(1)</sup></b>             | <b>\$0.7–1.0m</b>  | <b>\$1.6m</b> | Above guidance |
| <b>Adjusted NPAT<sup>(1)(2)</sup></b> | <b>\$2.0– 2.7m</b> | <b>\$2.9m</b> | Above guidance |

1. Excludes transaction costs of \$3.9m 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 Metrics acquisition
2. Excludes non-cash amortisation of intangibles recognised on acquisition of Metrics and Mayne Pharma Intl; notional interest on earn-out to Hospira; and non-cash LTI

### Operating performance

#### Metrics Products

The Metrics Products operating segment manufactures and distributes generic pharmaceutical products in the United States of America. Sales were \$5.2m and gross profit was \$3.5m for the period that Mayne Pharma owned the business.

Over the six months to 31 December 2012, the Metrics Products segment's sales were US\$19.8m, up approximately 50% on the pcp. The majority of this sales growth was through Metrics' distribution channel with the launch of Oxycodone capsules in August 2012 and growth in existing products such as Nystatin, a topical powder used to treat fungal infections. Metrics plans to increase its distribution of products through this channel as new generic products are approved and launched. In this six month period, 33% of the Metrics Products segment sales were made through this distribution channel, up from 10% in the pcp, with the remainder of sales made through exclusive long-term partnerships.

### **Metrics Contract Services**

The Metrics Contract Services segment provides contract pharmaceutical development services to third party customers principally in the USA. Sales were \$3.0m and gross profit was \$1.9m for the period that Mayne Pharma owned the business.

Over the six months to 31 December 2012, the Metrics Contract Services segment's sales were US\$12.4m up 6.8% on pcp driven by a solid year for fee for service clients. Metrics had approximately 100 active customers during 2012 of which 14 were new clients, up from 9 new clients in 2011.

### **Mayne Pharma Australia**

The Mayne Pharma Australia (MPA) segment manufactures, distributes and markets branded and generic products in the Australian market. Sales were \$4.8m for the 1H13, slightly down on pcp, however gross profit was up \$0.6m or 40.5% to \$2.1m. The improved gross margin was driven by a new pricing programme implemented across the portfolio in early 2012 and the transfer in house of the manufacture of aspirin tablets. The revenue derived from aspirin sales was impacted in the period by a 16% price decrease mandated by the PBS due to price discounting driven by competitor products to Astrix® and the launch of a new competitor, which resulted in minor market share loss.

Going forward, MPA will benefit from a number of initiatives to diversify the portfolio that were put in place by the management team during the half.

#### *Kapanol® acquisition*

On 14 December 2012, the Company announced the acquisition of Kapanol® and related assets from GlaxoSmithKline (GSK) which then became part of the MPA portfolio on 1 February 2013. Whilst sales of Kapanol® are now accruing to the Company, promotion will commence from May 2013 once the national sales team is in place. This is a significant milestone whereby Mayne Pharma will be calling on both specialists and general practitioners for the first time in our company's history.

#### *Injectable portfolio*

As announced in November 2012, the Company entered into two separate licensing and distribution agreements that give Mayne Pharma the right to distribute injectable products in the Australian market. One submission has been filed with the Therapeutic Goods Administration (TGA) for a product with current market sales of \$3m<sup>1</sup> and up to a further eleven submissions are planned for lodgement by the end of this calendar year with total current annual market sales of approximately \$70m<sup>1</sup>. The expected TGA approval time is typically between 12-14 months.

---

<sup>1</sup> IMS Health, MAT December 2012

### *Percutane® launched*

On 1 February 2013, the Company launched two new products, Percutane® Pain Relief Cream and Percutane® Sports Cream. These are natural, plant-based cream products sold over the counter (OTC) at pharmacies. Percutane® was originally developed by Clinical Technologies (NZ) Ltd in 1999 and licensed to Mayne Pharma in 2012. The Percutane® range will be manufactured, marketed and distributed by Mayne Pharma in Australia and these products will join the existing OTC range that includes Astrix® capsules ([astrixaspirin.com.au](http://astrixaspirin.com.au)) and Magnoplasm® ([magnoplasm.com.au](http://magnoplasm.com.au)). The topical joint and muscular pain market in Australia is valued at over \$50m<sup>1</sup> and growing at 5% per annum.

The launch of these products and the re-launch of Kapanol® are expected to lead to both a revenue and margin uplift of MPA in the coming years.

### **Mayne Pharma Global**

The Mayne Pharma Global operating segment manufactures and out-licences branded pharmaceuticals to international marketing and distribution partners and provides contract manufacturing services to third party clients in Australia. In 1H13, sales were \$14.1m, down \$7.9m or 35.9% on pcp and gross profit was significantly lower reflecting the reduction in sales of Doryx® in the USA following the launch of a generic product in May 2012. Excluding the impact of Doryx® in the US, sales were \$10.3m down \$0.7m on pcp resulting from a small contraction in contract manufacturing volumes and a phasing of customer orders into the second half.

The Company has resumed production of Doryx® and currently expects supply to normalise in 2H13 to more closely match the underlying prescription demand. Doryx® 150mg tablet prescriptions currently hold more than 60% market share in the US and Warner Chilcott remains committed to the dermatology area through retaining its national dermatology sales force.

### **Research and Development activities**

As a result of the Metrics acquisition, Mayne Pharma now has a diversified research and development pipeline with 17 products currently under development targeting markets with annual sales greater than US\$3bn<sup>2</sup>. The development program is focused on both complex generic and branded products employing various oral drug delivery technologies and other intellectual property know-how. The resulting portfolio is difficult to formulate or manufacture and therefore has, or is likely to have, inherently lower levels of competition.

### **Generic pipeline**

Metrics currently has four products filed with the FDA, with its first sustained release formulation to be filed in the next week. These five products are targeting markets with annual sales of greater than US\$400m<sup>2</sup>. Three of these products are expected to receive FDA approval and be launched during calendar 2013.

Of the remaining pipeline, the Company expects to file at least five more ANDA's (abbreviated new drug applications) by the end of this calendar year.

---

<sup>1</sup> IMS Health, MAT December 2012

<sup>2</sup> IMS Health, MAT September 2012

## **Branded pipeline**

In January 2013, the UK issued a Marketing Authorisation (MA) to SUBACAP® for the treatment of superficial and systemic fungal infections. This MA follows completion of the Decentralised Procedure in which the UK, as the Reference Member State, delivered a positive outcome for SUBACAP® along with the three Concerned Member States (CMS) of Germany, Spain and Sweden. The German, Spanish and Swedish CMS MAs are expected to be issued later in 2013.

The Company will now commence the 'repeat use procedure' to seek marketing approval in Italy, the largest itraconazole market in Europe. Approval in these five European countries will give access to more than half the European itraconazole market, valued at over US\$90m<sup>1</sup> per annum.

These MAs now place the Company in a strong position to secure suitable marketing and distribution partners in Europe where we plan to launch SUBACAP® in the coming year.

The Company will also be applying for marketing approval of SUBACAP® with the TGA in Australia in the coming month.

## **Integration of Metrics**

Project teams have been set up to focus on the key revenue generating combination projects including cross selling Mayne Pharma's approved and pipeline products in the US and cross selling Metrics' products in Australia and through Mayne Pharma's distribution network in Europe and Asia. We expect to announce by the end of this calendar year, the launch of a Mayne Pharma product in the US through Metrics' distribution channel and the filing in the US of a significant ANDA for a product that was developed at the Company's Salisbury site in South Australia.

## **Cash flow**

Net operating cash flow before tax and transaction costs was \$5.7m and total net cash flows from operating activities was an inflow of \$0.2m. Cash on hand at 31 December 2012 was \$30.4m, representing an increase of \$18.8m from 30 June 2012. Notable cash flows during the period included:

- \$84.4m in proceeds from the issue of shares for the Metrics and Kapanol® acquisitions,
- \$41.6m net proceeds from borrowings,
- \$102.9m payment to acquire Metrics on 13 November 2012,
- \$3.9m of acquisition related expenses, and
- \$1.1m in capital expenditure.

On 1 February, \$10.5m of cash was paid to GSK for the acquisition of Kapanol® and related assets. A final payment of \$3.4m will be paid to GSK on 3 February 2014.

---

<sup>1</sup> IMS Health, MAT September 2012

## **Outlook**

The Company remains on track to deliver full year results in line with the guidance announced at the time of the Metrics acquisition assuming current economic conditions prevail. The 2H13 is expected to benefit from a return to revenue growth of Doryx® on the 1H13 results and further revenue growth from price rises and volume growth in select products across the portfolio.

Many factors will influence the final result including the launch of any new products across the portfolio, exchange rates and the degree of normalisation of US Doryx® sales.

### **For further information contact:**

|                                      |  |
|--------------------------------------|--|
| Scott Richards (CEO)                 | 08 8209 2410                                     |
| Mark Cansdale (CFO)                  | 03 8614 7705                                     |
| Lisa Pendlebury (Investor Relations) | 0419 548 434,<br>lisa.pendlebury@maynepharma.com |