MAYNE PHARMA REPORTS 1HFY15 RESULT

26 February 2015, Melbourne Australia: Mayne Pharma Group Limited (ASX: MYX) is pleased to release its consolidated results for the half-year ended 31 December 2014.

Commenting on the result, Mayne Pharma's CEO, Mr Scott Richards said, "As clearly signalled at our November AGM, our first half was materially impacted by the lack of contribution from sales of US Doryx™ tablets to Actavis, a key product which is now controlled by the Company following the successful completion of the Doryx™ acquisition[1] on 24 February 2015. We are very excited about building this franchise under our ownership and delivering long-term value to Mayne Pharma. Following a transition period of approximately two months, Mayne Pharma will launch this product through its new US Specialty Brands Division and control the entire supply chain from manufacture, packaging and distribution, through to sales and marketing. Excluding sales of US Doryx™, the rest of the business grew 6% on the prior comparable period (pcp), driven by the key direct US generic products, our contract services business and Lozanoc™, our improved formulation of itraconazole."

Summary of results

1HFY15 Results			Change on pcp	
$m	1HFY15	1HFY14	$m	%
Revenue	**59.5**	**70.0**	**(10.5)**	**(15%)**
Gross margin	30.9	36.9	(6.0)	(16%)
GM%	*52.0%*	*52.8%*		
EBITDA(1)	14.6	19.1	(4.5)	(23%)
Adjustments(2)	(1.1)	(0.9)	(0.2)	26%
Reported EBITDA	13.5	18.2	(4.7)	(26%)
Depreciation / Amortisation	(5.0)	(5.0)	(0.0)	0.0%
Reported PBIT	8.6	13.2	(4.7)	(35%)
Net interest	(2.6)	(2.6)	(0.0)	0%
Income tax expense	(2.0)	(2.2)	(0.3)	(11%)
Reported NPAT	**4.0**	**8.4**	**(4.4)**	**(53%)**
EBITDA margin	25%	27%		
Cash at bank	19.1	19.8	(0.7)	(3%)

1. EBITDA is considered by Directors to be a meaningful measure of the operating earnings and performance of the Group and that this information may be useful for investors recognizing that it is a non-IFRS term.
2. Adjustments to EBITDA in 1HFY15 include $0.8m of start up costs in relation to the formation of a specialty brands division in the US business; $0.5m non-cash credit resulting from the decrease in the fair value of the Hospira earn-out liability associated with the Mayne Pharma International Pty Ltd (MPI) acquisition in November 2009; and the Company's share of the operating losses made by Hedgepath Pharmaceuticals during the period ($0.8m).

The Group recorded revenue of $59.5m, down 15% on pcp. Gross margin was 52.0% compared to 52.8% in the prior half and the reported profit after tax was $4.0m down from $8.4m in the pcp. Reported earnings before interest, tax, depreciation and amortisation (EBITDA) was $13.5m and underlying EBITDA (excluding certain specified expenses) was $14.6m, down 23% on pcp. These results are consistent with the preliminary trading update provided to ASX on 10 February 2015.

[1] Mayne Pharma acquired the Doryx™ brand and related assets from Actavis plc for US$50m in the United States and will establish a US Specialty Brands Division to be staffed with a field team of 66 professionals operational from May 2015 to support the sales and marketing of Doryx™

The fall in sales and earnings reflects the reduction in sales of US Doryx™ tablets that was foreshadowed at the time of the release of the full year results in August last year and again at the 2014 Annual General Meeting in November.

Operating performance

US Products (USP)

The US Products operating segment's sales were $27.3m, down 1% on 1HFY14 and gross profit was $17.3m up 2% on 1HFY14. Sales of the Company's directly-distributed products grew 26% to US$17.6m whilst third party sales decreased 41% to US$6.7m.

Direct sales through USP's own distribution operations continue to increase and represented more than 72% of USP sales in the six months to 31 December 2014, up from 55% in the pcp.

The growth in directly-distributed products was driven by higher sales of BAC[2], doxycycline, erythromycin and oxycodone, which benefited from either higher volume demand or price increases. The launch of oxycodone HCl oral solution and selegiline HCl tablets in the period has been successful and new accounts have been secured.

Third party-distributed products such as liothyronine and oxycodone underperformed during the period as previously outlined at the 2014 Annual General Meeting. The drop in third party oxycodone sales followed sustained poor performance of the distributor and liothyronine faced increased competitive pressures following the launch of a new competitor into this market. The Company is working closely with its distributors to incentivise and improve performance and expects stabilisation and a greater contribution to earnings from these products in 2HFY15.

Going forward, the Company also expects this segment will benefit from increased market penetration of existing directly distributed products, the launch of Potassium Chloride Powder for Oral Solution commencing in March 2015, the improved profit share arrangements recently announced for BAC capsules and Methamphetamine tablets and the launch of select third party-distributed products under the Mayne Pharma label.

Metrics Contract Services (MCS)

The Metrics Contract Services segment's sales were $15.1m up 10% on 1HFY14 and gross profit was $7.4m up 22% on 1HFY14. This segment continues to perform well and the key indicators, including the number of quotes written, quotes signed and committed business, were up by more than 20%. MCS supports more than 100 customers worldwide in the pharmaceutical and biotechnology sectors with approximately 75% being repeat customers. During the period, MCS introduced eight new clients.

Mayne Pharma International (MPI)

MPI's sales were $19.1m, down $9.0m or 32% on the pcp, and gross profit was down 46% reflecting the lack of US Doryx™ sales. Excluding US Doryx™ shipments, the rest of the MPI business grew 34% with the generic doxycycline and erythromycin products that were launched

[2] Butalbital/APAP/Caffeine

in the US and Lozanoc™ being the strongest performers. Lozanoc™ revenues grew from sales in both Spain and Australia and also benefited from additional licensing fee income. In Spain, Lozanoc™ now has greater than 10% market share of the itraconazole capsule market due to the successful efforts of ISDIN, the Company's marketing and distribution partner. The launch in further European markets will follow completion of the repeat use procedure which is expected in 1HFY16.

MPI's Australian portfolio continues to expand with 19 products now approved by the TGA up from just seven products two years ago. The majority of the newly approved products are injectable and the Company is pleased to report it has now been successful in several tender submissions over the last six months. Injectable revenues though modest to date are expected to become a material component of the MPI segment in the mid-term. In addition, Kapanol™, Lozanoc™ and the over-the-counter (OTC) products such as Licener™ and Magnoplasm Splintex™ are expected to drive the growth of this segment going forward.

Pipeline

The Company continues to commit substantial resources to advancing its pipeline as research and development is a key pillar to delivering long-term growth. Investment in research and development in 1HFY15 was $8.7m with 86% of this spend directed to generic products. Although, the spend was lower than pcp, this was driven primarily by a reduction in clinical trial costs related to the timing of projects following the significant number of US Food and Drug Administration (FDA) filings made late FY14. Several of the new development projects added to the US pipeline were also higher-value products requiring more complex development.

The Company currently has 16 products pending approval at the FDA and ten products pending approval at the Therapeutic Goods Administration (TGA) in Australia. In addition, the Company has more than 15 products under active development targeting US markets with sales of US$4bn.

Approval times at the FDA continue to lengthen due to the growing backlog of filings. Current median Abbreviated New Drug Applications (ANDA) review times are estimated at 3.5 years. The Company currently has:

- 3 products filed with the FDA for over 2 years targeting addressable markets valued at US$60m,
- 7 products filed with the FDA for over 1 year targeting addressable markets valued at over US$1bn, and
- 6 products filed in the last year targeting addressable markets valued at over US$0.7bn.

The FDA has granted priority review for the Company's generic version of Tikosyn® (Dofetilide capsules) as it is a paragraph IV ANDA. Furthermore, the Company also separately announced on 25 February 2015 that Pfizer, Inc. has withdrawn its legal action in respect of this product, enabling Mayne Pharma to enter the US market following FDA approval and prior to the October 2018 expiration of Pfizer's patent. The Company expects to be awarded a 180-day exclusivity period upon approval.

Lozanoc™ - anti-fungal

The Company continues to progress the commercialisation of Lozanoc™ globally and is currently finalising the regulatory filing in the United States which it expects to lodge in 1HFY16. In Korea and China, the Company is working with its marketing and distribution partners to finalise clinical trials that will support the regulatory filings.

SUBA-Itraconazole - oncology

The Company is working with US-based HedgePath Pharmaceuticals, Inc (Hedgepath) who are pursuing the clinical development, registration and commercialisation of SUBA™-Itraconazole in anti-cancer applications. In December 2014 HedgePath received FDA clearance of its Investigational New Drug (IND) Application for a Phase IIb study in patients with a particular skin cancer sub-type called Gorlin Syndrome and plans to start dosing patients later this year. Industry sources estimate there are approximately 10,000 patients in the US with this skin cancer sub-type and the average cost to treat each patient is US$60,000 per year implying an annual market value of US$0.5bn. Assuming success with the Gorlin's indication, HedgePath plans to extend its development program to include other cancer types focused on selected lung and prostate cancers.

Kapanol™ - breathlessness

In November 2014, Mayne Pharma signed an agreement with Flinders University, South Australia, to license intellectual property surrounding research relating to the use of Kapanol™, for the treatment of dyspnoea (chronic breathlessness). A Phase III efficacy trial[3] is currently underway with results expected by the end of FY15. This program is another example of the Company's strategy to repurpose existing drugs where possible into new therapeutic fields.

Other

Going forward the Company will be increasing its investment in the development of branded products and if approved by the FDA these products would be marketed by the Company's new US Specialty Brands division. These projects will be an important part of the Company's strategy to diversify its business model across both branded and generic products with the objective of improving long-term shareholder value.

Cash flow

Net operating cash flow before interest and tax was $10.6m and total net cash flows from operating activities was an inflow of $8.5m after including $0.3m of tax payments and $1.9m of net interest payments.

Cash on hand at 31 December 2014 was $19.1m representing an increase of $4.3m from 30 June 2014. The Company had borrowings of $58.9m and has complied at all times with the related covenants. During the period the key notable cash flows were $8.7m in payments for product development, $1.5m in capital expenditure across the Group; and $3.5m net proceeds

[3] A randomised double-blind multi-site parallel arm controlled trial expected to involve the recruitment of over 200 patients to assess relief of refractory breathlessness comparing fixed doses of morphine and placebo (MOPS Study). The MOPS study has been designed to confirm the efficacy of low-dose morphine sulphate using Kapanol™ capsules.

from borrowings.

Outlook

The Company is pleased to announce it completed the acquisition of the US Doryx™ assets from Actavis this week on 24 February. This is a transformational deal for Mayne Pharma and will materially change the scale and potential of the business in terms of earnings and cash flows. The outlook over the coming year is very positive and significant growth opportunities exist for the Company across multiple channels and business segments in the US – the world's largest pharmaceutical market.

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About Mayne Pharma

Mayne Pharma is an ASX-listed specialty pharmaceutical company that develops and manufactures branded and generic products, which it distributes globally; either directly or through distribution partners and also provides contract development and manufacturing services.

Mayne Pharma has a 30-year track record of innovation and success in developing new oral drug delivery systems and these technologies have been successfully commercialised in numerous products that have been marketed around the world.

Mayne Pharma has two drug development and manufacturing facilities based in Salisbury, SA, Australia and Greenville, NC, USA with expertise in formulation complex oral dose forms including highly potent compounds, controlled substances, modified release products and inherently unstable compounds.