ASX Announcement

MAYNE PHARMA REPORTS 1HFY14 RESULT

26 February 2014, Melbourne Australia: Mayne Pharma Group Limited (ASX: MYX) is pleased to release its consolidated results for the half year ended 31 December 2013.

The Group recorded total revenue of $70.7m, up 158% on the prior corresponding period (pcp) and up 25% on the 2HFY13. The reported profit before tax was $10.6m up from a loss of $1.5m in the pcp and the net profit after tax was $8.4m, up from a reported loss in the prior period.

Reported earnings before interest, tax, depreciation and amortisation (EBITDA) was $18.2m and underlying EBITDA (excluding certain specified expenses) was $19.1m, up 254% on pcp and 47% on the 2HFY13.

The operating results in the pcp include Metrics, Inc. (Metrics) for the six weeks from 14 November 2012, whilst the 2HFY13 period includes Metrics for the full period and therefore provides a better comparison on the operating performance of the Group.

Summary of results

1HFY14 Results			Change on pcp	
$m	1HFY14	1HFY13	$m	%
Sales revenue[1]	**70.0**	**27.0**	**42.9**	**159%**
Gross margin	36.9	11.9	25.0	210%
GM%	*52.8%*	*44.1%*		
EBITDA[2]	19.1	5.4	13.7	254%
Adjustments[3]	(0.9)	(4.1)	3.3	(79%)
Reported EBITDA	18.2	1.2	17.0	1,364%
Depreciation / Amortisation	(5.0)	(2.1)	(2.9)	138%
Reported PBIT	13.2	(0.8)	14.1	NM
Net interest[4]	(2.6)	(0.6)	(2.0)	304%
Income tax expense	(2.2)	(1.1)	(1.1)	108%
Reported NPAT	**8.4**	**(2.5)**	**11.0**	**NM**
EBITDA margin	27%	20%		
R&D investment	10.8	3.1	7.7	251%
Cash at bank	19.8	18.9	0.9	5%

1. Sales revenue excludes other revenue of $0.8m
2. 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 and is a non-IFRS term.
3. Adjustments to EBITDA in 1HFY14 include $0.2m of acquisition costs, $0.3m for the non-cash charge arising from the increase in the fair value of the earn-out liability associated with the Mayne Pharma International Pty Ltd (MPI) acquisition in November 2009 and a $0.4m provision for the proposed settlement agreement entered into by Warner Chilcott, Mayne Pharma and the direct purchaser class of plaintiffs in the Doryx anti-trust action in the USA.
4. Includes finance expenses $2.2m, notional non-cash interest expense of $0.5m representing the charge for the unwinding of the discount on the earn-out for the MPI acquisition less interest revenue $0.1m.

Mayne Pharma's CEO, Mr Scott Richards said, "I am very pleased with the strong uplift in operating performance of all segments in this half. The Group result reflects the impacts from

recent business and product acquisitions, new product launches, increased market penetration of existing products and more favourable exchange rates. Margins have improved materially with underlying EBITDA margins increasing from 20% in the pcp to 27%."

"Investment in research and development was up 250% to $10.8m reflecting our commitment to expanding and diversifying our new product portfolio. The Company now has ten ANDA[1] products pending approval at the US Food and Drug Administration (FDA) and twelve products pending approval at the Therapeutic Goods Administration (TGA). The Company is continuing to progress the commercialisation of its pipeline and expects to file more than six products with the US FDA, six products with the TGA and one product with the Korean FDA in the coming year."

Operating performance

US Generic Products

The US Generic Products (USGP) operating segment sales were $27.5m, up 37% on 2HFY13 and gross profit was $17.0m up 38% on 2HFY13.

The key drivers of growth were the acquisition of Libertas Pharmaceuticals in July 2013 and increased market penetration of the directly distributed products including Nystatin and the Oxycodone HCl combination products. In addition, sales of generic Doxycycyline Hyclate Delayed Release (DR) tablets and Erythromycin DR capsules, launched in July 2013 were the first revenue synergies to materialise from the Metrics acquisition and made a material contribution to earnings in the half.

Direct sales through USGP's own distribution operations continue to increase and now represent more than 47% of USGP sales in the six months to 31 December 2013, up from 32% in 2HFY13.

Excluding exchange rate impacts, USGP had sales of US$25.4m for the 1HFY14, which was up 24% on 2HFY13.

During the period, the Company significantly expanded its product portfolio, which now consists of 20 products in more than 50 dose forms and strengths across a range of therapeutic categories, up from 10 products at the end of 1HFY13.

Metrics Contract Services

The Metrics Contract Services segment sales were $13.7m up 16% on 2HFY13 and gross profit was $6.0m up 33% on the 2HFY13. Excluding exchange rate impacts, Contract Service sales were up 5% on 2HFY13 to US$12.6m.

Contract Services continues to secure new business in a competitive marketplace under the new leadership team. This segment has improved its key performance measures in the half with the number of quotes written and quotes signed up by more than 10% on pcp. The quote conversion rate also improved and was 58% in this period up from 55% in pcp. Metrics continues to service approximately 100 customers and introduced seven new clients in the half.

[1] ANDA - Abbreviated New Drug Application

Mayne Pharma Global (MP Global)

MP Global's sales were $21.4m up $7.3m or 52% on the pcp and gross profit was up 141% reflecting the launch of the 200mg Doryx™ tablet in the US.

Doryx™ is sold in the US through the Company's marketing and distribution partner, Actavis (formerly Warner Chilcott), who are committed to maintaining and growing their dermatology franchise. The 200mg tablet launch has been a success in its first six months and now represents more than 80% of Doryx™ branded prescriptions. With three years of exclusivity granted by the FDA, the Company is confident that the branded Doryx™ franchise will continue to make a solid contribution to earnings in the coming year.

Excluding the sales of Doryx™, MP Global sales were down slightly following reduced contract manufacturing volumes and a reduction in the sales of Kapanol™ following the acquisition of the Australian rights from GSK in February 2013. Australian Kapanol™ sales are now captured as part of the MPA segment.

Mayne Pharma Australia (MPA)

MPA's sales were $6.9m, up $2.1m or 44% on the pcp. Gross profit was up $1.1m or 52% on pcp to $3.2m. The improved performance of MPA was driven largely by the addition of the Kapanol® product into the MPA portfolio.

The Company has now owned the Kapanol™ franchise for 12 months and has recruited a national sales force to promote the product, which began operation in the field in May 2013. This team of seven have logged over 4,000 calls/visits to physicians and are having a meaningful impact on reversing the 10-year decline in sales of this product in worked territories.

The remainder of the MPA portfolio is showing mixed growth. Astrix™ tablets and capsules were up on pcp with grocery sales contributing to the rise. Percutane™ pain relief cream also made a contribution to this segment following its launch in February 2013. This was offset by Doryx™ capsules which were down on pcp following annual mandated PBS price decreases.

The Company will be launching Licener™, a new natural plant-based head lice treatment shortly and is expecting to launch Lozanoc™ (formerly SUBACAP™) and a range of injectable products pending TGA approval in 2014. The first injectable product has just recently been approved by the TGA.

In addition, the Company has an active development and in-licensing program and is on track to file a Metrics-sourced pain product as well as a number of other in-licensed injectable products with the TGA during 2014.

Pipeline

The Company continues to expand its pipeline of new products under development both in Australia and the US. The Company now has ten products pending approval at the FDA and twelve products pending at the TGA.

The investment in product development increased $7.7m to $10.8m in 1HFY14 with 69% of the investment capitalised over the period in accordance with Australian Accounting Standards.

The investment in developing generic products accounted for 86% of this spend with the remainder allocated to the continued development of branded products.

The Company continues to progress the commercialisation of Lozanoc™ globally:

- In South Korea, the 4th largest itraconazole market in the world, a supply and distribution agreement has been signed with Boryung Pharmaceutical Company. Under the exclusive distribution agreement, Mayne Pharma will receive an upfront payment, milestone payments upon meeting certain regulatory hurdles and a percentage of net sales. Product launch is subject to approval of Lozanoc™ by the Korean Ministry of Food and Drug Safety. Mayne Pharma and Boryung have a long-standing relationship that dates back more than 20 years through the out-licensing of Astrix™ DR low-dose aspirin in the Korean market;

- In Australia, the Company applied for marketing approval of Lozanoc™ with the TGA and is on track for approval in mid 2014. MPA has commenced preparations for market launch;

- In Europe, the Company is preparing for market launch in select countries and expects to see the first sales of Lozanoc™ by the end of FY14; and

- In Japan and China, the Company is continuing to progress discussions with potential marketing partners.

Cash flow

Net operating cash flow before interest, tax and transaction costs was $18.9m and total net cash flows from operating activities was an inflow of $14.6m after including $0.2m of transaction costs, $2.2m of tax payments and $1.8m of net interest payments.

Cash on hand at 31 December 2013 was $19.8m representing an increase of $0.9m from 30 June 2013. The Company had borrowings of $55.5m and has complied at all times with the related covenants.

Notable cash flows during the period included:

- $10.8m in payments for product development;
- $8.9m from loan draw downs;
- $2.0m in loan repayments;
- $1.5m in capital expenditure across the Group;
- the $11.3m earn-out payment for the Metrics acquisition;
- the $1.0m payment to acquire Libertas on 2 July 2013; and
- the $0.5m payment to acquire the ZEBUTAL™ trademark.

Outlook

The Company will continue to diversify its business globally across products, drug delivery technologies and geographies and will pursue further business, product and brand acquisitions, in-licensing and out-licensing activity.

Ongoing investment in research and development with a particular focus on expanding the US generic pipeline is expected to drive the business in the medium term.

In the US, new product launches including the recently launched 150mg Doxycycline Hyclate DR tablet, improved market share of existing products, continued focus on building the Contract Services platform and the recent acquisitions of ZEBUTAL™, LORCET™ and ESGIC™ will drive this business forward. The Company remains confident that the FDA will approve some of the filed products in the coming 12 months, although timing remains uncertain.

MP Global is expected to see the first sales of Lozanoc™ in Europe in the second half of FY14 and Doryx™ is expected to continue to be the major contributor to earnings in this segment in 2014.

In Australia, the Company continues to expand and diversify the portfolio with a particular focus on the pain franchise, building an injectable portfolio and expanding the range of over-the-counter products. MPA is expected to benefit from new product launches and improved performance of existing products such as Kapanol™ in the coming year.

For further information contact:

Scott Richards +61 3 8614 7777
Lisa Pendlebury +61 419 548 434, lisa.pendlebury@maynepharma.com

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, 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.