

MAYNE PHARMA REPORTS RECORD FY14 RESULT

27 August 2014, Melbourne Australia: Mayne Pharma Group Limited (ASX: MYX) is pleased to release its consolidated results for the year ended 30 June 2014.

The Group recorded total revenue of \$143.3m, up 72% on the prior corresponding period (pcp) and gross profit was up 92% to \$75.1m. Reported earnings before interest, tax, depreciation and amortisation (EBITDA) was \$43.1m and underlying EBITDA (excluding certain specified expenses) was \$40.4m, up 120% on pcp.

The reported profit before tax was \$28.0m and the net profit after tax was \$21.3m, up from a reported loss in the prior period.

Summary of results

FY14 Results \$m	FY14	FY13 ¹	Change on pcp	
			\$m	%
Revenue	143.3	83.4	59.9	71.7%
Gross profit	75.1	39.0	36.1	92.5%
GM%	52.4%	46.7%		
EBITDA ⁽²⁾	40.4	18.4	22.0	120.0%
Adjustments ⁽³⁾	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%
Reported PBIT	33.2	1.9	31.3	1647.4%
Net interest ⁽⁴⁾	(5.2)	(2.6)	(2.6)	100.0%
Income tax expense	(6.7)	(2.1)	(4.6)	219.0%
Reported NPAT	21.3	(2.8)	24.1	NM
EBITDA margin	28.2%	22.0%		
R&D investment	19.8	10.9	8.9	82.4%
Cash at bank	14.8	18.9	(4.1)	(21.7%)

1. Includes Metrics, Inc. (Metrics) from 14 November 2012.

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. The non-IFRS information has not been audited.

3. Adjustments to EBITDA in FY14 include \$0.8m of acquisition costs, \$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 acquisition.

4. Includes finance expenses of \$4.3m, notional non-cash interest expense of \$1.1m representing the charge for the unwinding of the discount on the Hospira earn-out less interest revenue \$0.3m.

Mayne Pharma's CEO, Mr Scott Richards said, "The Group result reflects the impacts from recent business and product acquisitions, new product launches, increased market penetration of existing products and licensing fee revenue from the out-licensing of our products to a number of parties. Margins have improved materially with the underlying EBITDA margin increasing from 22% in the pcp to 28%. All operating segments performed well with both sales



and gross profit up on pcp and the second half sales and profit performance was stronger than the first half result across the Group.”

“Investment in research and development was up 82% to \$19.8m reflecting our commitment to expanding and diversifying our product portfolio. It is very pleasing to report the Company has significantly expanded its on-market product portfolio globally and now distributes 27 molecules across more than 80 different presentations.”

“In June 2014, the Company received its first US generic product approval since acquiring Metrics 20 months ago. The US Food and Drug Administration (FDA) approved Oxycodone Hydrochloride Oral Solution for the management of pain in the 100mg/5ml strength, targeting an addressable market of US\$40m¹. In Australia, the Therapeutic Goods Administration (TGA) approved Lozanoc™, our improved formulation of Itraconazole and the Company's first injectable product, Doxorubicin Hydrochloride.”

“In regards to the pipeline, the Company has 17 products pending approval at the FDA which is a significant change from a year ago when the Company had just seven pending products at the FDA. In Australia, the Company has 16 submissions pending approval at the TGA.”

Operating performance

US Products

The US Products operating segment (USP) revenue was \$56.9m, up \$31.7m or 126% on FY13 and gross profit was \$32.0m up 103% on FY13.

The key drivers of growth were the full year contribution from the Metrics acquisition (the prior year included Metrics for 7.5 months), the acquisition of Libertas Pharma Inc. (Libertas) in July 2013, the ZEBUTAL™ brand acquisition, the launch of generic Doxycycline Hyclate Delayed-Release (DR) tablets and Erythromycin DR capsules and further market penetration of directly distributed products such as Nystatin and Oxycodone capsules.

In US dollar terms, USP had sales of US\$52.2m for FY14 which was up 30% on the full 12 month period to 30 June 2013. Direct sales through USP's own distribution operations continue to increase and represent 56% of USP sales, up from 33% in FY13.

Gross profit margin was down from 63% to 56%, which was impacted by the addition of the Libertas products which are third party sourced at lower net margins, and reduced royalties from products distributed by third parties.

¹ IMS Health MAT June 2014



Metrics Contract Services

The Metrics Contract Services segment (MCS) revenue was \$28.4m up \$13.6m or 92% on FY13 and gross profit was \$13.0m up 101% on FY13. In US dollar terms, MCS sales were US\$26.0m up 6% on the 12 months to 30 June 2013. The reported results for the prior period only included MCS for 7.5 months.

MCS has delivered a solid result under new leadership and reinvigorated sales efforts. Key performance measures improved over the corresponding full 12 month period to 30 June 2013 with the number of quotes signed up 30%, quote conversion rate (the number of quotes signed as a percentage of quotes written) has improved to 65%, up from 56% in the prior period and MCS has introduced 17 new clients in FY14 up from 11 in the prior period.

During the year, the Company made a number of investments in new formulation and analytical service-related equipment, which has supported the growth of this segment.

Mayne Pharma International (formerly MP Global and MPA)

The Mayne Pharma International (MPI) segment revenue was \$61.2m up \$16.8m or 38% on the pcp and gross profit was up 82% to \$31.3m reflecting the launch of the 200mg Doryx™ tablet in the US, the additional contribution from Kapanol™ and licensing fee income.

The largest product in this segment is branded Doryx™, which is sold in the US through the Company's marketing and distribution partner, Warner Chilcott (acquired by Actavis in October 2013). US branded Doryx™ sales to Warner Chilcott were up 60% on pcp to US\$21m due to inventory build and the launch of the 200mg which was approved by the FDA in April 2013. Although the 200mg dose strength now represents more than 97% of prescriptions written, weekly volumes are averaging around 5,000 TRx per week, down approximately 30% on peak volumes in November 2013.

The first commercial sales of Lozanoc™ occurred in Spain in June, with ISDIN, the Company's marketing and distribution partner, promoting the product through its 200+ dermatology focused sales force. Lozanoc™ launched in Australia in August 2014 under the Mayne Pharma label and will launch in additional European countries during the coming year.

The Company received licensing fee income during the year from the out-licensing of SUBA™-Itraconazole to HedgePath (\$4.5m) and Lozanoc™ (\$0.4m) to Boryung (South Korea), ISDIN (Spain, Italy, Portugal) and Glenmark (UK). The agreement with Glenmark has since been terminated and Mayne Pharma is in the process of identifying an alternate path to market in the UK.

The other parts of the MPI segment had mixed results with morphine (Kapanol™ and Kadian™) sales up 37% on pcp to \$7.1m, aspirin (Astrix™ and generic aspirin) sales up 5% to \$8.1m while contract manufacturing sales were down 15% to \$9.8m.



Cash flow

Net operating cash flow before interest, tax and transaction costs was \$34.3m and total net cash flows from operating activities was an inflow of \$26.1m after including \$0.8m of transaction costs, \$3.7m of tax payments and \$3.7m of net interest payments.

Cash on hand at 30 June 2014 was \$14.8m representing a decrease of \$4.1m from 30 June 2013. The Company had borrowings of \$48.0m and has complied at all times with the related debt covenants.

Notable cash flows during the period included:

- \$19.8m in payments for research and development;
- \$8.8m in-flow from the additional borrowings;
- \$6.4m in loan repayments;
- \$17.5m of net proceeds from the issue of shares;
- \$4.2m payments for capital expenditure across the Group;
- \$14.7m of earn-out payments for the Metrics and Mayne Pharma International acquisitions;
- \$11.4m in payments to acquire the ESGIC™, LORCET™ and ZEBUTAL™ trademarks
- settlement of the \$3.3m deferred payment for the Kapanol™ acquisition; and
- \$0.8m payment to acquire Libertas on 2 July 2013.

Pipeline

The Company continues to expand its pipeline of products under development both in Australia and the US. The Company now has more than 60 products under development of which 17 products are pending approval at the FDA targeting an addressable market with sales greater than >US\$1.8bn² and 16 products are pending approval at the TGA targeting an addressable market with sales greater than >A\$150m². Of the 17 products pending at the FDA, nine are DEA³ regulated molecules, three utilise modified release technologies and four have no current generic competitors.

The investment in research and development increased \$8.9m to \$19.8m in FY14 with 82% of the investment capitalised over the period in accordance with Australian Accounting Standards. Investment in developing generic products accounted for 90% of this spend with the remainder allocated to the continued development of branded products.

The Company continues to expand its business development program which has led to the finalisation of the following agreements:

- Out-licensed Lozanoc™ to ISDIN S.A. in Spain, Portugal and Italy;
- Out-licensed Lozanoc™ to A-med GmbH in Austria;
- Out-licensed Lozanoc™ to Boryung Pharmaceutical Co in South Korea;

² IMS Health MAT June 2014

³ Drug Emergency Agency

- Out-licensed Lozanoc™ to NovoTek Therapeutics in China⁴;
- Out-licensed SUBA™-Itraconazole intellectual property to HedgePath Pharmaceuticals;
- In-licensed four generic injectable products from Gland Pharma (India) to launch in Australia;
- In-licensed two generic products from Demo S.A. (Greece) to launch in Australia;
- In-licensed a modified release opioid pain product from a European speciality pharmaceutical company to launch in Australia;
- In-licensed a generic product from Wanbang Biopharmaceuticals (China) to launch in Australia;
- In-licensed four generic injectable products from Genfarma Laboratorio (Spain) to launch in Australia⁴;
- Signed a memorandum of understanding to distribute generic Temozolomide in the US with IDT Australia⁴; and
- Acquired the rest of world rights to Kapanol™ back from GSK⁴.

The Company continues to progress discussions with potential Lozanoc™ partners in Japan, South America and other major markets and has begun Kapanol™ out-licensing discussions for select markets.

Outlook

The Company expects to grow its revenue and underlying earnings in the coming year with US Products and Metrics Contract Services being the key contributors to the growth, whilst the MPI segment is expected to decline.

The US Products segment is expected to benefit from the recent product acquisitions (ESGIC™, LORCET™ and ZEBUTAL™), further growth in the generic doxycycline franchise, new product launches including Oxycodone Hydrochloride Oral Solution and increased market penetration of select generic products. The Company remains confident that the FDA will approve some of the 17 filed products in the coming 12 months, although timing remains uncertain.

Metrics Contract Services is positioned well for the year ahead with key performance indicators such as the number of quotes written and signed as well as committed business pipeline trending strongly.

The MPI segment is expected to be down year on year driven by reduced branded US Doryx™ sales reflecting the recent lower underlying prescription volumes and anticipated resultant destocking at Actavis and lower licensing fee income. Excluding Doryx™ and licensing fees, the MPI segment sales and gross profit is expected to be up driven by Kapanol™, Lozanoc™ and the launch of additional injectable products in Australia.

The Company will continue to diversify its business globally and investment in research and development is expected to drive the business in the medium term.

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⁴ Signed in July 2014



ASX Announcement

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.

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