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MAYNE PHARMA REPORTS FY15 RESULT

- Transformational US Doryx™ acquisition completed for US\$50m
- New business created – US Specialty Brands (SBD) with a 60+ person sales team to promote specialty brands in the US
- Brought US distribution in-house for generic Methamphetamine and Oxycodone product family
- FDA approval of 50mg Doryx tablets and TGA approval of 12 products
- Advanced pipeline of 17 products filed with the FDA, two further products filed in FY15
- Significant first-to-file opportunity for Tikosyn™ generic capsules with settlement reached with Pfizer
- 2H15 underlying EBITDA performance up 49% on 1H15 with Doryx, directly-distributed US generic products and Metrics Contract Services driving this growth
- Balance sheet strengthened with net debt of \$2.6m at 30 June 2015, down from \$39.7m at 31 December 2014; cash of \$59.2m
- Significant growth expected in FY16 driven by recent product acquisitions, new product launches, increased market penetration of existing products and accelerated growth in Metrics Contract Services

Mayne Pharma's CEO, Mr Scott Richards said, "FY15 was a transformational period for Mayne Pharma with the acquisition of the Doryx brand and distribution rights which diversified the US business platform into an integrated pharmaceutical business with growth platforms in generics, contract services and now specialty brands."

"Following a soft first half, the Company's performance was substantially stronger in the second half with revenue up 37%, underlying EBITDA up 49% and underlying NPAT up 49% on the first half¹. The weaker first half reflected the lack of contribution from sales of Doryx tablets to Actavis as reported in February 2015. Despite this, US Doryx contributed \$18m to consolidated revenue (FY14: \$22.8m), which represents a combination of direct sales by the SBD team, transition profit and third party revenue. The gross profit contribution from US Doryx for the four months under Mayne Pharma's ownership was stronger than that recorded for the whole of FY14."

Summary of FY15 financial results

\$m	FY15	FY14	Change on pcp	2H15	1H15	Change 2H/1H
Revenue	141.4	143.3	(1%)	81.9	59.5	37%
Gross profit	80.0	75.1	7%	49.1	30.9	59%
GM%	56.6%	52.4%		59.9%	52.0%	
EBITDA – underlying ¹	36.4	40.4	(10%)	21.8	14.6	49%
EBITDA – reported	31.3	43.1	(27%)	17.8	13.5	32%
NPAT – underlying ²	13.4	17.8	(25%)	8.0	5.4	49%
NPAT – reported ²	7.8	21.3	(64%)	3.8	4.0	(6%)

¹ Adjustments to EBITDA include include \$4.5m one-off costs associated with set up of SBD, \$0.7m of acquisition costs; \$2.2m non-cash charge resulting from the increase in the fair value of the Hospira earn-out liability; \$2.8m credit to remove P&L impact of HedgePath; and \$0.5m restructure cost associated with transfer of warehouse from Montgomery to Greenville. Adjustments to NPAT include the tax effects of these items.

² NPAT is profit attributable to members of the Company and reconciliation of underlying NPAT is detailed in accompanying FY15 Results Presentation.



Excluding US Doryx revenue and one-off licensing fee income, group revenue was up 7% on the prior corresponding period (pcp) driven by Metrics Contract Services and directly-distributed US generic products.

Operating performance

US Products

The US Products operating segment (USP) performed strongly with sales at \$67.7m, up \$10.8m or 19% on FY14 and gross profit was \$36.2m up 13% on FY14.

The key drivers of growth were the part-year contribution from the Doryx acquisition (US\$7.9m from re-launch in May 2015) and growth in the key generic product franchises. This was offset by the performance of third party-distributed generic products, several of which were brought in-house late in the second half to improve the contribution of these products.

In May 2015, the Company brought the distribution of Methamphetamine and Oxycodone products in-house and also acquired full ownership of the Methamphetamine and BAC³ ANDAs during FY15 enabling the Company to control the manufacture, distribution and sales of these products and increase the economic benefit that flows to Mayne Pharma. It is expected these products will be key drivers of growth going forward.

In US dollar terms, USP revenue was up 9% to US\$56.6m with sales of directly-distributed products (excluding Doryx) up 21% to US\$35.1m and third party-distributed products were down 41% to US\$13.6m. The Oxycodone franchise was responsible for the majority of the third party decline year on year.

Gross profit margin was down from 56% to 53%, which reflects the fact that the margin on the branded Doryx and authorised generic sales in the US is split between USP, which records the distribution margin, and MPI, which records the manufacturing margin. If USP captured all the margin on a vertically integrated segment basis, the gross profit margin would have been 70%.

Metrics Contract Services

The Metrics Contract Services segment (MCS) outperformed industry growth, with revenue of \$33.8m up \$5.4m or 19% on FY14 and gross profit was \$17.0m up 31% on FY14. Revenue and gross profit margin increases are the result of improved pricing, operational efficiencies and a higher proportion of higher margin formulation development work in FY15. In US dollar terms, MCS sales were US\$28.3m up 9% on pcp.

Key performance measures continue to improve with the number of quotes signed up 9% on pcp and the amount of signed work in dollar terms up 19% on pcp. The quote conversion rate (the number of quotes signed as a percentage of quotes written) was 66% and MCS has introduced 19 new clients in FY15 up from the 17 added in the prior period. The committed business pipeline also continues to grow strongly. In the last two years, the customer base of MCS has increased 25% to 125 active clients.

³ Butalbital/APAP/Caffeine Capsule



Mayne Pharma International

The Mayne Pharma International (MPI) segment revenue was steady at \$60.7m down just 1% on pcp and gross profit improved 9% to \$34.2m.

This segment captured US Doryx third party revenue to February 2015, as well as the profit that arose during the transition period from Actavis to Mayne Pharma, and the manufacturing margin on in-market and intercompany sales.

Excluding US Doryx and one-off licensing fee income, MPI revenue increased 6% driven by increased sales of Erythromycin into the US, Kapanol™/Kadian™ into international markets following the acquisition of rest of world rights in July 2014 from GSK, and Suba™-Itraconazole into Spain. In Australia, the on-market product portfolio increased from 8 to 15 products over the year with the first sales of Lozanoc™ and six injectable products. In Spain, Itragerm™ (the local name for Lozanoc) became the market leader in the Itraconazole market with 17% market share by volume in the 2H15.

Cash flow

The Company ended the year in a solid financial position with net debt of \$2.6m. Cash on hand at 30 June 2015 was \$59.2m representing an increase of \$44.4m from 30 June 2014. The Company had borrowings of \$61.8m which increased \$13.7m largely reflecting foreign exchange movements during the period whereby the translation of USD balances at 30 June 2015 was at 0.796 versus the prior period at 0.943.

Following the successful debt refinancing programme completed in June, the Company has materially reduced its cost of funds with the margin on the base rate (US Libor) falling from 5.75% to 1.5% on drawn funds and has more flexible and less onerous terms and conditions. The business now has greater financial flexibility to use alternate sources of capital to fund its growth with operating cash, US\$75m of undrawn line facility and a A\$10m working capital facility.

Net operating cash flow before interest, tax, SBD set up and transaction costs was \$39.1m up \$4.8m on pcp and above underlying EBITDA, due to favourable benefits from movements in working capital in the period. Total net cash flows from operating activities was an inflow of \$22.4m after including \$3.9m of net interest payments, \$7.6m of tax payments, \$4.5m of SBD set up costs and \$0.7m of transaction costs.

Notable cash flows during the period included:

- \$16.7m in payments for research and development;
- \$114m of net proceeds from the issue of shares;
- \$4.2m payments for capital expenditure across the Group;
- \$64.3m in payments to acquire Doryx; and
- \$11.9m of earn-out and deferred settlement payments for various other acquisitions.



Pipeline

The Company continues to commit substantial resources in terms of people and research and development spend to developing and advancing its pipeline globally. In FY15, the Company invested \$16.7m in research and development of which 80% was capitalised over the period to be amortised in the future in accordance with accounting standards.

In addition to this, the Company invested US\$2.5m in HedgePath Pharmaceuticals Inc. during the year to accelerate the clinical development program using Mayne Pharma's patented oral formulation of Itraconazole to treat certain cancers. A Phase IIb study in Gorlin's Syndrome (a rare form of skin cancer) is currently underway with results expected in late FY16.

The Company now has more than 30 pipeline products in the US, of which 17 are pending approval at the FDA targeting an addressable market with sales greater than >US\$1.8bn⁴. The Company is now in active dialogue with the FDA on six of these filings including the generic version of Tikosyn (Dofetilide capsules). Mayne Pharma settled the Tikosyn litigation with Pfizer during FY15 and expects to be awarded 180-days of market exclusivity upon approval by the FDA.

In Australia, the Company has more than 20 pipeline products of which six have been recently approved by the TGA and expected to launch in 1H16 and a further seven products are pending approval at the TGA.

The Company also continues to advance the pipeline of branded products, which are an important part of the strategy to diversify the business across both branded and generic products. Commercialisation of Lozanoc is continuing with the out-licensing of the product in a further nine countries: Argentina, Belgium, China, Chile, Columbia, France, Germany, Mexico and Peru. The next launch of Lozanoc will be in Germany later this calendar year via ISDIN, the Company's marketing and distribution partner. In the US, the Company is finalising the regulatory filing and expects to lodge the dossier during FY16.

Also during FY15, the Company signed an agreement with Flinders University in South Australia to license intellectual property surrounding research relating to the use of Kapanol for the treatment of respiratory dyspnoea (chronic breathlessness). Further clinical studies targeting US registration are planned to start in FY16.

⁴ IMS Health MAT June 2015



ASX Announcement

Outlook

The Company is now set for a period of strong earnings growth driven by recent product acquisitions, new product launches, increased market penetration of key product franchises and accelerated growth of the contract service business.

The new SBD division is established and actively promoting Doryx 50mg and 200mg tablets to dermatologists. This segment will capture a full-year contribution of Doryx in FY16. As outlined in the Doryx acquisition presentation on 10 February 2015, the Company expects the monthly EBITDA contribution of the Doryx franchise to approximate US\$2.7m on average during FY16.

MCS has started the year in a solid position with all key performance indicators trending favourably. With an enlarged customer base and a solid pipeline of committed business MCS is positioned well for the future.

Growth of the US generic products division is expected to accelerate with Methamphetamine, the Oxycodone franchise, BAC, Hydrocodone/APAP and Erythromycin being the key drivers.

Locally, MPI will benefit from growth in the Australian-marketed portfolio including a stronger contribution from the growing injectable product offering, further growth in the OTC portfolio and the launch of oxycodone immediate release tablets, the first Metrics-acquired product approved in Australia.

In addition, the Company maintains an active program to identify potential acquisition targets to further expand the product portfolio and will continue to look at opportunities through FY16 to diversify the product portfolio and business.

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