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MAYNE PHARMA REPORTS STRONG 1HFY16 RESULT

- Revenues of \$127.3m, an increase of 114% on 1HFY15
- Underlying EBITDA of \$43.3m, up 197% on 1HFY15
- Reported EBITDA of \$40.7m, up 201% on 1HFY15
- Reported net profit after tax was \$19.2m, up 380% on 1HFY15
- Net operating cashflow of \$30.5m, up 259% on 1HFY15
- Exceeded Doryx™ EBITDA guidance of an average of US\$2.7m/month over 1HFY16
- Business positioned to deliver continued financial growth across FY16 driven by opportunities across multiple channels and all business segments

Commenting on the result, Mayne Pharma's CEO, Mr Scott Richards said, "We are pleased to report an exceptionally strong half with increases in revenue, EBITDA, net profit and operating cashflow over the 1HFY15."

"All three US-based segments contributed significantly to growth in both US dollar and Australian dollar terms. Our US generic division delivered outstanding growth with nine of the top ten molecules growing sales versus the prior corresponding period (pcp) and Metrics Contract Services' growth was well above industry rates. The Doryx™ acquisition, completed in February 2015 has been successfully integrated and delivered earnings ahead of expectations set at that time. The 50mg Doryx™ tablet launched in August 2015 is continuing to grow with prescriptions now tracking above 1,500 per week."

"The Company continues to invest in its facilities and product pipeline. The dual-site expansion to materially enhance both manufacturing capacity and capability announced in August 2015, remains on track for completion in FY18. The Company also significantly increased its investment in research and development focusing on products with intrinsic barriers to entry that utilise our capabilities in potent compounds, controlled substances and advanced drug delivery technologies such as SUBA™ and multi-particulate controlled-release."

Summary of results ⁽¹⁾

\$m	1HFY16	1HFY15	Change on pcp	
			\$m	%
Revenue	127.3	59.5	67.8	114%
Gross profit	80.4	30.9	49.5	160%
GM%	63.2%	52.0%		
EBITDA - underlying ⁽²⁾	43.3	14.6	28.7	197%
EBITDA - reported	40.7	13.5	27.2	201%
NPAT - underlying	20.4	5.4	15.0	278%
NPAT - reported	19.2	4.0	15.2	380%
Net operating cashflow	30.5	8.5	22.0	259%

1. NPAT and EBITDA is profit attributable to members of the Company.

2. Adjustments to EBITDA in 1HFY16 include a \$5.2m non-cash credit resulting from the decrease in the fair value of earn-out liabilities; \$6.7m payment to settle a dispute with a former distributor; and \$1.2m reflecting HedgePath Pharmaceuticals losses attributable to members of the Company. Reconciliation of underlying NPAT is detailed in accompanying 1HFY16 Results Presentation which includes the tax effect of these adjustments.



Operating performance

Generic Products Division (GPD)

The GPD operating segment's sales were \$44.6m, up 64% on 1HFY15 and gross profit was \$26.4m up 48% on 1HFY15. In US dollar terms, sales were up 33% to US\$32.3m with directly-distributed generic products up 52% to US\$26.7m and third-party distributed products decreased 18% to US\$5.6m reflecting the fact that several products were brought in-house during 2015. Direct sales through GPD's own distribution operations now represent 83% of GPD sales in the six months to 31 December 2015, up from 72% in the pcp.

Key growth franchises during the period included BAC¹, oxycodone, hydrocodone, methamphetamine and liothyronine with these molecules benefiting from higher volume and/or increased prices. The gross profit margin declined from 65% to 59% reflecting lower margins on the hydrocodone and oxycodone franchises which participate in more competitive markets and reduced royalties from third party partnerships.

Two new generic launches occurred during the half with a BAC tablet launched in August and BACCP¹ capsule launched in December. These two products participate in markets with sales of approximately US\$150m² according to IMS Health.

Specialty Brands Division (SBD)

The new SBD segment captures the sales of promoted branded products, which in the 1HFY16 comprised the 50mg and 200mg Doryx™ tablets. The SBD operating segment's sales were \$43.4m and gross profit was \$38.1m in the 1HFY16. In US dollar terms, SBD's revenue was US\$31.4m and EBITDA exceeded the guidance of US\$2.7m/month that was announced at the time of the Doryx™ acquisition in February 2015.

In terms of the in-market performance of Doryx™, the franchise averaged more than 5,000 prescriptions per week over the half, capturing 9% share of the addressable tetracycline market³. The newly launched 50mg Doryx™ tablet has now become a material component of the Doryx™ franchise with leading edge prescription volume tracking at more than 1,500 per week.

Metrics Contract Services (MCS)

The MCS operating segment's sales were \$23.5m up 55% on 1HFY15 and gross profit was \$12.4m up 68% on 1HFY15. In US dollar terms, MCS performed well ahead of industry growth rates with sales up 26% to US\$17m reflecting the very successful efforts of the sales team to diversify the customer base and increase the proportion of higher value, later stage development work. During the half, 11 new clients were added and the committed business pipeline grew 21%.

Favourable market conditions in the contract services industry has seen growth strengthen to high single digits in calendar 2015 driven by expanding R&D portfolios across the pharmaceutical and biotech sectors and the increased trend towards outsourcing early stage development work particularly for advanced drug delivery technologies requiring specialised expertise.

¹ BAC (Butalbital/Acetaminophen/Caffeine) and BACCP (Butalbital/Aspirin/Caffeine/Codeine Phosphate)

² IMS Health, December 2015

³ Addressable tetracycline market captures Doryx™, other tetracyclines prescribed for acne and their generic equivalents



Mayne Pharma International (MPI)

MPI's sales of \$15.8m were flat on pcp and gross profit was \$3.5m down 24%. Australian sales grew 11% to \$12.9m driven by the launch of a number of new products including a range of injectable products and a generic oxycodone tablet, which was a product obtained through the Metrics acquisition, and further growth in over-the-counter products such as Astrix™ and Licener™. International sales were down 34% to \$2.8m driven by softer sales of Astrix™ to our Korean partner who faced difficult local market conditions. In other international regions our Lozanoc™ and Kapanol™ franchises continue to grow.

Pipeline

Mayne Pharma's global development pipeline consists of over 50 products of which more than 35 are targeting US markets with sales greater than US\$7bn⁴. The Company continues to commit substantial resources to advancing this pipeline. Investment in research and development in 1HFY16 was \$14.2m with 75% of this spend directed towards generic products. The US pipeline includes a range of products with intrinsic barriers to entry and includes 10 modified release products, 11 controlled substances and 6 potent compounds. The Company introduced five new US pipeline products during the period targeting markets with sales greater than US\$600m⁴.

In the US, the Company has 18 products pending approval at the FDA targeting markets with sales of US\$2bn⁴. Seven of these pending products have now received 2016 target action dates, up from zero twelve months ago.

The most significant generic pipeline product is the Company's filing for dofetilide capsules, which is a paragraph IV product and first-to-file market opportunity. This product is now in the final stages of the FDA's review and the Company expects to be awarded 180 days of generic market exclusivity following approval, which is expected to occur this calendar year. This market continues to grow in both volume and price terms with leading edge sales of US\$180m⁴.

The Company continues to progress the commercialisation of Lozanoc™ globally and continues to work with its marketing and distribution partners in 15 countries to support the product on-market or to gain regulatory approval.

Cash flow

Net operating cash flow before interest and tax was \$44.4m and total net cash flows from operating activities was an inflow of \$30.5m after including \$13.1m of tax payments and \$0.8m of net interest payments.

Cash on hand at 31 December 2015 was \$49.7m representing a decrease of \$9.5m from 30 June 2015. During the period the key notable cash flows were \$14.2m in payments for product development (both expensed and capitalised), \$6.6m in capital expenditure across the Group, \$5.2m payments for product acquisitions and \$17.7m in earn-out payments.

The Company had borrowings of \$64.8m at 31 December 2015 and complied at all times with the related covenants.

⁴ IMS Health, December 2015



Outlook

The outlook remains very positive and the Company has significant growth opportunities across multiple channels and business segments.

The Company expects growth to continue in the 2HFY16 through expansion of the on-market portfolio globally, commercialising the pipeline of products recently approved and further business development activities to in-license or acquire products. The Company has an active program to identify potential acquisition targets with strong growth potential, complementary assets and technology and are strategically compelling to create long-term shareholder value.

The Company is confident it has the right team and strategies in place to protect the Doryx™/doxycycline franchise in the event of generic competition on the 200mg tablet. Having both a specialty brand and generic business offers the Company a dual channel strategy to optimise performance of this important franchise.

Metrics Contract Services is also expected to perform strongly across FY16 with key performance indicators such as committed business pipeline and quote dollars written and signed all trending favourably.

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About Mayne Pharma

Mayne Pharma is an ASX-listed specialty pharmaceutical company focused on applying its drug delivery expertise to commercialise branded and generic pharmaceuticals. Mayne Pharma also provides contract development and manufacturing services to more than 120 clients worldwide.

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 product development and manufacturing facilities based in Salisbury, Australia and Greenville, USA with expertise in formulation of complex oral dose forms including highly potent compounds, controlled substances, modified release products and inherently unstable compounds.