



25 August 2017

MAYNE PHARMA REPORTS FY17 RESULTS

- Revenue of \$572.6m, an increase of 114% on FY16
- Underlying EBITDA of \$206.5m, up 133% on FY16
- Reported EBITDA of \$204.0m, up 165% on FY16
- Reported net profit after tax was \$88.6m, up 137% on FY16
- Basic earnings per share of 6.2c, up 30% on FY16
- Positive operating cash flow in 2H17 of \$51.9m

Mayne Pharma's CEO, Mr Scott Richards said, "All key performance metrics have increased significantly versus the prior year driven by product acquisitions in our Generic Products and Speciality Brands businesses, new product launches and continuing strong growth in Metrics Contract Services. Revenue grew 114% to \$572.6m, underlying EBITDA grew 133% to \$206.5m and reported NPAT grew 137% to \$88.6m."

Summary of results¹

\$m	FY17	FY16	Change on pcp	
			\$m	%
Revenue	572.6	267.3	305.3	114%
Gross profit	315.8	168.4	147.4	88%
GM%	55%	63%		
EBITDA – underlying ²	206.5	88.5	118.0	133%
EBITDA – reported	204.0	76.9	127.1	165%
NPAT – underlying	90.2	45.2	45.0	100%
NPAT – reported	88.6	37.4	51.2	137%
Basic EPS (cents)	6.2	4.8		30%

1. NPAT and EBITDA is profit attributable to members of the Company. 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. The IFRS information is still in the process of being audited.
2. Adjustments to reported FY17 EBITDA include \$22.4m net patent litigation gains (\$26.2m of patent settlement income less \$3.8m of litigation expenses relating to Mayne Pharma's allegation that Merck's Noxafil® product infringes a Mayne Pharma patent); \$20.2m intangible asset impairment; \$5.6m of transaction and other related costs; \$5.3m credit for the revaluation of HPPI warrants; \$1.5m of legal costs associated with the US Department of Justice investigation and \$2.9m to remove the HedgePath Pharmaceuticals Inc. (HPPI) losses attributable to members of the Company.

As previously foreshadowed at the market update on 8 August 2017, the Group reported results have been impacted by the \$25m non-cash (pre-tax) charge largely relating to intangible asset impairment and reassessment of the useful life of the acquired Teva portfolio assets to 15 years.

The reduction in revenue and EBITDA since the market update reflects a US\$6.6m adjustment following a detailed review of chargebacks, rebates and sales allowances as part of the year end procedures. This late change to the accounts was a result of an unrecorded liability that relates to complex acquisition accounting for the acquired Teva portfolio which impacted the entire Generic Products business unit.

"The Company successfully launched 50 new products in the US and Australia of which 37 were acquired from Teva Pharmaceutical Industries Limited and Allergan plc (acquired Teva portfolio). Another six generic products were launched in the US with the first-to-market doxycycline hyclate immediate-release (IR) tablets (generic Acticlate®) achieving 100% return on investment of all development costs in the first week of shipments. The launch of three patent-protected dermatology products Doryx® MPC (doxycycline delayed-release), Fabior® (tazarotene foam) and



Sorilux[®] (calcipotrene foam) drove a much stronger performance in the second half for Specialty Brands and Mayne Pharma International benefited from four product launches.”

“Metrics Contract Services delivered another excellent result reflecting the high growth CDMO¹ market, growing customer demand for end-to-end analytical and pharmaceutical development solutions and operational efficiencies. The facility investments in Greenville are attracting later stage business with Metrics Contract Services now able to support clients’ future commercial manufacturing needs.”

“Whilst the Company is facing competitive pricing pressures in the US retail generic market, it is focused on executing a number of growth initiatives to offset these headwinds including accelerating growth of Specialty Brands through the expansion of our dermatology sales force, diversifying channels to market, growing share of marketed products, extracting product cost savings from optimising our supply chain network, bringing new products to market and further business development activity. With strong positive operating cash flow expected in FY18, together with low gearing and significant available liquidity, the Company retains flexibility to invest in further growth initiatives.”

Operating Performance

Generic Products Division (GPD)

The GPD operating segment’s sales were \$418.7m, up 292% on FY16 and gross profit was \$218.3m up 259% on FY16. In US dollar terms, sales were up 306% to US\$315.6m driven by the acquisition of the Teva portfolio and strong performance of the underlying business with dofetilide being the key driver of growth, up 400% year on year to US\$56m. Key new product launches were doxycycline hyclate IR tablets and butalbital/acetaminophen tablets. Gross profit margins declined over the year, impacted by increased competition on a number of products driven by customer consolidation and accelerated approvals by the FDA; and increased stock obsolescence.

The acquired Teva portfolio achieved sales of US\$180.4m, gross profit margins in excess of 50% and EBITDA of US\$90.4m. Product transfers of 27 acquired Teva products are advancing and expected to lead to improved product margins through accessing lower supply prices. Annual cost savings of US\$12m are expected to be generated from these product transfers by FY19.

Specialty Brands Division (SBD)

The SBD operating segment’s sales were \$61.9m, down 20% on FY16 and gross profit was \$58.6m down 20% reflecting the loss of market exclusivity on Doryx 50mg and 200mg in May 2016. In US dollar terms, SBD’s sales were US\$46.6m.

The launch of Fabior and Sorilux in January 2017 drove the stronger performance in the 2HFY17 versus the 1HFY17 with sales up 31% in USD terms. In the latest week of prescription data, total prescriptions written for Fabior were 1,476² and for Sorilux were 287². Both products are tracking ahead of the acquisition business case and expected to exceed in FY18 the original three-year sales guidance given at the time of the acquisition.

¹ Contract Development and Manufacturing Organisation

² IMS Health, 4 weekly average TRx / week as at 11 August 2017



ASX Announcement

The in-market performance of the 50mg and 200mg Doryx franchise has tracked well over the year continuing to hold onto more than 65%³ of total market prescriptions written following the generic event. The launch of Doryx MPC in August 2016 contributed to growth of the overall Doryx franchise across the 2QFY17, highlighting the promotional responsiveness of this product.

To accelerate the growth of Specialty Brands, the Company has commenced an expansion of its sales force from 60 to 120 speciality sales representatives. Following the successful launch of Doryx MPC in August 2016 and Fabior and Sorilux in January 2017, the Company is confident it can further accelerate market share and the contribution of these three patent-protected dermatology brands as well as supporting any future brands that are added to the dermatology portfolio.

Metrics Contract Services (MCS)

The MCS operating segment's sales were \$57.8m up 18% on FY16 and gross profit was \$32.1m up 22% on FY16. In US dollar terms, sales were up 22% to US\$43.6m, well ahead of US CDMO industry growth rates of 6-7% per annum⁴. The strong financial performance reflects the increased prevalence of later stage, higher margin development work and ongoing operational efficiencies.

Construction of the new solid oral dose manufacturing facility and the now-operational stability centre in Greenville, along with investments in new technical equipment, has assisted the Company in securing more business as well as creating a pipeline of commercial contract manufacturing business.

The analytical laboratory efficiency program created additional capacity and a 20% increase in revenue per employee. A key highlight during the year was MCS supporting a New Drug Application (NDA) filing for a client that, if approved, will be manufactured at the Greenville facility.

Mayne Pharma International (MPI)

The MPI operating segment's sales were \$34.3m up 2% on FY16 and gross profit was \$6.8m down 13% on FY16. Australian sales benefited from increased sales of Lozanoc[®] (SUBA[®]-Itraconazole) and oxycodone tablets but were negatively impacted by reduced injectable and Kapanol[®] (morphine) sales. Rest of world sales grew 6% driven by a rebound of Astrix[®] (aspirin) sales in Korea. The decline in gross profit reflects reduced one-off licensing fee income and international Kapanol royalties.

Pipeline

Mayne Pharma continues to invest in the development of generic and new branded products focusing on higher value and niche product opportunities, first-to-market generics, hard-to-manufacture products and complex formulations. The Company invested \$35m in research and development over the year and in-licensed several products with increased differentiation, including an intravaginal contraceptive device and a motion sickness transdermal delivery system patch.

³ IMS Health, 4 weekly average TRx / week as at 11 August 2017

⁴ Pharmsource



ASX Announcement

Mayne Pharma's development pipeline includes over 40 products targeting US markets with sales greater than US\$6.5bn⁵. The Company has 19 products pending approval at the FDA with a total market value of more than US\$1bn⁵. During the year, in the US, the Company added 14 products to its pipeline targeting markets with sales greater than US\$1.8bn⁵, filed five products with the FDA and received FDA approval for four generic products.

Recent strategic alliances have expanded the Company's research and development capabilities into more complex development and manufacturing dosage forms. Formulytica, a Melbourne based contract development organisation, is providing a platform for the development of medical dermatology foam products; Douglas Pharmaceuticals, a New Zealand based pharmaceutical company is providing access to semi-solid, soft-gel products requiring high containment manufacturing; and Corium, a biopharmaceutical company, is providing access to its drug delivery technology in the form of transdermal patches.

In Australia, the Company launched three in-licensed injectable products and Myxazole[®] (clotrimazole/hydrocortisone cream) and received Therapeutic Goods Administration approval for a new brand product Urorec[®] (Silodosin) capsules, indicated for relief of lower urinary tract symptoms associated with benign prostatic hyperplasia in adult men. Urorec was launched in August and is being marketed by Mayne Pharma's specialty sales team.

The Company continues to progress the commercialisation of its patented formulation of itraconazole for the treatment of certain fungal conditions and as a potential treatment for certain cancers. SUBA-Itraconazole capsules are now sold in Australia, Spain and Germany and have successfully captured 22% volume market share of the Australian itraconazole capsule market⁶ and 32% volume market share in Spain⁷. Further country launches are expected in the coming year in Europe and South America. In the US, the Company is completing further clinical studies to support the NDA filing and, if approved, would be marketed through the Specialty Brands business unit.

HedgePath Pharmaceuticals Inc. (HPPI), a partly owned subsidiary (53.5% ownership) of Mayne Pharma, reported positive interim results from its ongoing Phase IIb clinical trial in patients with a genetic form of skin cancer called Basal Cell Carcinoma Nevus Syndrome (BCCNS), more commonly known as Gorlin Syndrome. These interim results suggest that SUBA-Itraconazole provides an effective and safe alternative to address the unmet medical need for non-surgical treatment. HPPI will now be undertaking further detailed analyses of the individual tumour responses from this ongoing trial to verify the robustness of SUBA-Itraconazole in reducing the target tumour burden in BCCNS patients. The program qualified for the FDA's Orphan Drug Designation in 2016.

In June 2017, Mayne Pharma executed a global licensing agreement with Nestlé Skin Health (parent entity of leading global dermatology and skin health franchise, Galderma) to develop and commercialise a new chemical entity, trifarotene, in rare disease indications. Trifarotene is a new retinoid developed by Galderma and formulated as a topical cream which has potent keratolytic properties making it a potentially viable treatment for a number of rare skin diseases. In 2014, the FDA granted Orphan Drug Designation for trifarotene in the treatment of the skin disease congenital ichthyosis, a group of skin scaling disorders. The collaboration with Galderma highlights Mayne Pharma as a trusted partner in dermatology while accelerating the Company's clinical and market development capabilities in the management of rare diseases.

⁵ IMS Health, MAT Jun 2017

⁶ IMS Health, Jun 2017 quarter

⁷ IMS Health, Dec 2016 quarter



Debt and Cash Flow

The Company ended the year with net debt of \$277m. Cash on hand at 30 June 2017 was \$63m and the Company had borrowings of \$340m.

The significant working capital investment made in the first half for the acquired Teva portfolio has now stabilised and the Company achieved positive net operating cash flow after interest, tax, working capital and one-off items in the second half of \$51.9m.

Net operating cash flow for FY17 was an outflow of \$15.2m after including \$57.6m of tax payments, \$10.0m of net interest payments, \$180.9m net working capital investment and \$17.7m net inflow from one-off items. Other notable cash flows during the period include \$35.0m payments for product development (expensed and capitalised), \$104.4m in capital expenditure, \$951.7m in payments for product acquisitions and \$13.9m in earn-out and deferred settlement payments.

The strategic investments at Salisbury, South Australia and Greenville, North Carolina are on track to be completed in 2018 to support the pipeline of products under development, the transfer of ten Teva products and commercial contract manufacturing.

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 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 100 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 formulating complex oral dose forms including highly potent compounds, controlled substances, modified release products and inherently unstable compounds.

Acticlate® and Noxafil® are registered trademarks of third parties.