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MAYNE PHARMA REPORTS FY19 RESULTS

- Revenues of \$525.2m, down 1% on prior corresponding period (pcp)
- Reported gross profit of \$289.9m, up 13% on pcp
- Reported EBITDA of \$111.6m, a decrease of 4% on pcp
- Adjusted EBITDA of \$130.9m, a decrease of 20% on pcp
- Reported Net loss of \$280.8m impacted by intangible asset impairments
- Net operating cashflow of \$106.6m
- Launched two specialty brand products in the US, TOLSURA® (SUBA®-itraconazole) capsule and LEXETTE™ (halobetasol) foam and five generic products
- Strong growth from Specialty Brands with sales and gross profit doubling
- Business positioned for a stronger FY20 driven by growth of TOLSURA and LEXETTE, accelerated growth of Metrics Contract Services, new generic product launches and improved operating performance

Mayne Pharma's CEO, Mr Scott Richards said, "Whilst the last two years have been extremely challenging for our business due to competitive pressures in the US generic market, we have undertaken a number of actions to better align our business with market realities and focused the business on sustainable categories and channels. These changes position Mayne Pharma well for the future to reduce earnings volatility and drive shareholder returns."

"Specialty Brands had a very strong year doubling sales and gross profit with FABIOR®, SORILUX®, DORYX® franchise and LEXETTE all contributing to growth versus pcp. Metrics Contract Services and Mayne Pharma International also performed well with double digit sales growth in AUD terms. Whilst reported gross profit grew 13%, EBITDA was impacted by greater investment in expensed research and development and commercial infrastructure to support the recent brand launches."

Summary of results¹

\$m	FY19	FY18	Change on pcp	
			\$m	%
Reported revenue	525.2	530.3	(5.1)	(1%)
Reported gross profit	289.9	256.5	33.4	13%
<i>GM%</i>	<i>55%</i>	<i>48%</i>		
Reported EBITDA	111.6	116.8	(5.2)	(4%)
Reported net loss	(280.8)	(133.9)	(146.9)	(110%)
Underlying EBITDA ²	130.9	163.5	(32.4)	(20%)
Cash flow from operations	106.6	121.5	(14.9)	(12%)

1. Earnings attributable to members of the Company with exception of cash flow which is consolidated.

2. Adjustments to EBITDA in FY19 include \$5.5m non-cash credit arising from an increase in the fair value of earn-out liabilities, \$2.7m of legal costs associated with drug pricing investigations, \$11.2m to remove HedgePath Pharmaceutical Inc. (HPPI) losses and non-cash fair value restatement of HPPI warrants.

As foreshadowed at the May 2019 trading update, the Company completed a detailed review of the Company's intangible assets taking into account current and projected market dynamics. This has resulted in a non-cash (pre-tax) charge of \$351.7m relating largely to the intangible generic assets. This impairment resets the balance sheet, improves reported profit in future periods and is in line with US generic peers who have also undertaken sizeable impairments of their generic intangible assets in recent years. Mayne Pharma has also streamlined its generic development



activities in FY19, abandoning non-viable projects and focused portfolio selection and product development expertise on opportunities that align with core therapeutic channels.

"We remain committed to our key strategic initiatives which are centred on providing value to patients and prescribers in dermatology, women's health and infectious disease through the provision of an innovative offering of complementary branded and generic products in each therapeutic category. This year saw the completion of several business development activities including the acquisition of two dermatology products – LEXETTE (halobetasol) foam and generic EFUDEX® (fluorouracil) cream, as well as a distribution agreement to add two pipeline dermatology products leveraging our established channel infrastructure. We also received FDA approval for TOLSURA (SUBA-itraconazole) anti-fungal capsule which launched in the US in January this year through a new hospital-based field team."

Operating Performance

Specialty Brands Division (SBD)

The SBD operating segment's sales were \$91.6m, up 105% on FY18 and gross profit was \$79.8m up 113% on pcp. In US dollar terms, SBD's sales were US\$65.5m, up 89% on FY18 and gross profit was US\$57.1m, up 96% on pcp.

The Company continues to grow its on-market dermatology business through improved sales force effectiveness and new launches. All products contributed to growth benefiting from the dermatology sales team expansion in 2018 with FABIOR up 54%, SORILUX up 26% and the DORYX family up 153% versus pcp in USD terms. The strong growth in DORYX reflects elimination of the abnormal one-off DORYX returns which impacted the prior period and favourable product sales mix. Adjusting for DORYX returns in the prior period, SBD sales were up 48% in FY19 on pcp. The launch of LEXETTE in February also contributed to the growth with total weekly prescriptions averaging 680 across the June 2019 quarter.

Generic Products Division (GPD)

The GPD operating segment's sales were \$320.8m, down 17% on FY18 and gross profit was \$164.5m, down 7% on pcp impacted by competitive pressure on key products. In US dollar terms, sales were US\$229.4m down 23% on FY18 and gross profit was US\$117.7m down 14% on pcp. There were a number of one-off items that impacted the results in the 2HFY19 including failure-to-supply penalties and shelf stock adjustments from pricing changes.

Dofetilide sales were impacted significantly by the launch of a number of new competitors with sales down by more than 80% to US\$13m driven by pricing pressure, market share loss and shelf stock adjustments. Excluding dofetilide, GPD sales were down 7% and gross profit up 8% respectively on pcp in US dollar terms. Liothyronine sales whilst up 86% on pcp to US\$43m, were down 42% in the 2HFY19 versus the 1HFY19 due to new competition.

The Company continues to make progress on lowering its product cost base through product transfers in-house or into third party contract manufacturing organisations. Approximately US\$15m of annual cost savings are expected to be realised with the majority of these savings expected in FY21.



Metrics Contract Services (Metrics or MCS)

The MCS operating segment's sales were \$72.2m, up 14% on FY18 and gross profit was \$35.5m up 6% on pcp. In US dollar terms, sales were up 6% on pcp to US\$51.6m.

Metrics continues to have a healthy pipeline of committed business including a growing pipeline of commercial manufacturing revenues from clients who are transferring FDA approved products into Greenville or have products in development or pending at regulatory agencies around the world. In June, an MCS client gained Japanese (PMDA) approval for a Greenville developed and manufactured product, which is the first international drug approval for the site. This product is expected to launch in the 1QFY20 and is also pending at 6 other regulatory agencies around the world.

During FY19, Metrics added three commercial manufacturing clients up from just one in the prior period with manufacturing revenues now representing 5% of sales and expected to grow strongly in FY20. Over time, Metrics is expected to transition from a predominantly project-based revenue stream to include a mix of recurring revenue from commercial manufacturing.

Mayne Pharma International (MPI)

The MPI operating segment's sales were \$40.7m up 10% on FY18 and gross profit was \$10.0m up 25% on pcp. MPI benefited from growing sales of SUBA-itraconazole and KAPANOL® globally, new third-party contract development revenues and milestone payments from the out-licensing of key specialty products globally.

Two new Chinese distribution agreements were signed with Yung Shin Pharm to register and distribute ASTRIX® low dose capsules and with Novotek Pharmaceuticals to register and distribute KAPANOL® sustained release capsules.

Pipeline

Mayne Pharma's strategy is to continue to expand its on-market portfolio in dermatology, women's health and infectious disease to fully leverage the innovative patient-centric distribution channels the company has been developing. In FY19 research and development spend was \$50.3m of which more than 75% was directed towards programs in these three therapeutic areas.

The Company has three women's health contraceptive generic products in its pipeline targeting markets with IQVIA sales of US\$1.1b including a generic NUVARING®, which is the largest contraceptive sold in the US\$5.5b¹ US contraceptive market with no generic equivalents today.

In terms of the brand programs, 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 is a proprietary, patented formulation that enhances the solubility and absorption of conventional itraconazole formulations. SUBA-itraconazole was launched in the US, Argentina, Mexico and Italy during the year to treat fungal infections and is now sold in seven countries.

The Company also assumed full control of the SUBA-itraconazole Basal Cell Carcinoma Nevus

¹ IQVIA MAT Sales Jun 2019



ASX Announcement

Syndrome (BCCNS) program from HPPI and plans to commence a phase III pivotal clinical trial in FY20. The Company has recently commenced a phase II program with trifarotene in another rare disease - congenital ichthyosis with the first patient dosed in August 2019. In addition there are a number of other ongoing clinical trials assessing the efficacy and tolerability of new indications or label extensions for products like SUBA-itraconazole, FABIOR, LEXETTE and SORILUX, some of which are investigator initiated studies.

Mayne Pharma's generic pipeline includes more than a dozen products pending approval at the FDA, including three products with no generic equivalents today.

Debt and Cash Flow

The Company achieved positive net operating cash flow after interest, tax and working capital of \$106.6m down 12% on the prior period. Significant cash flow items during the period include \$29.1m increase in working capital driven by an extension of trading terms in the first half by one of the major wholesalers, \$21.0m in net tax receipts and \$13.5m in net interest payments.

The Company had net debt of \$280.4m which declined \$18.0m during the 2HFY19, cash on hand of \$89.0m and retains significant room within its bank covenants, with leverage at 2.0x and shareholders' funds of approximately \$1.0b.

Outlook

In FY20, the Company expects stronger results driven by the specialty brand launches of TOLSURA and LEXETTE in the US, growth of the generic and proprietary dermatology and women's health portfolios and accelerated growth of Metrics Contract Services driven by additional technical team members, the expanded analytical, development and manufacturing footprint in Greenville and delivery of the pipeline of committed business.

The Company is targeting eight new product launches by the end of CY20 with a market value of US\$1.4b according to IQVIA, of which two are already approved.

In addition, various initiatives at the Company's manufacturing sites in Greenville and Salisbury are expected to drive greater operational efficiencies and improved financial performance across FY20 and beyond. The Company also expects to further optimise its cost base through reducing operating expenses via more controlled spending and realising significant cost savings from product transfers in house or to new contract manufacturers.

The Company will continue to reposition the business towards specialty branded products, contract services and sustainable generic portfolios and channels to produce more durable and less volatile earnings streams.



ASX Announcement

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About Mayne Pharma

At Mayne Pharma we believe that everyone deserves medicines that are better, safe and more affordable. That's why our people are determined to create innovative products and services for our changing world.

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 formulation of complex oral and topical dose forms including potent compounds, modified-release products and inherently unstable compounds.

EFUDEX® and NUVARING® are registered trademarks of third parties.