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MAYNE PHARMA REPORTS FY18 RESULTS UNDERPINNED BY A SIGNIFICANTLY STRONGER SECOND HALF

- Significantly improved trading in 2HFY18 with adjusted EBITDA up 35% to \$95m on 1HFY18 driven by the rebound of generic products
- Positive operating cash flow of \$121.5m with 2HFY18 operating cashflow up 53% on 1HFY18
- Expanded Specialty Brands field team to 114 sales representatives which has contributed to the growth of Fabior® and Sorilux® in the second half
- Launched six generic products in the US, filed eight products with the US Food and Drug Administration (FDA) including generic NuvaRing® and a New Drug Application (NDA) for SUBA®-Itraconazole anti-fungal capsule
- Metrics Contract Services delivered three consecutive years of double digit revenue growth in USD and received its first commercial contract manufacturing revenues
- Strategic manufacturing investments at Salisbury, South Australia and Greenville, North Carolina now complete with several generic products transferred in-house during the year which have contributed to improved product margins in the second half

Mayne Pharma's CEO, Mr Scott Richards said, "Following a challenging first half, the Company's performance was substantially stronger in the second half with revenue up 18%, adjusted EBITDA up 35%, adjusted NPAT up 171% and operating cashflow up 53%. Generic Products and Specialty Brands improved results were driven by a stabilising generic market, new product launches, cost savings from in-house manufacture of select products, portfolio optimisation and growing share of key marketed products. As expected, the extraordinary one-off items we reported in the first half for stock obsolescence and Doryx® returns have normalised to industry standard levels in the second half."

Summary of results¹

\$m	FY18	FY17	Change on pcp	2H18	1H18	Change 2H/1H
Revenue	530.3	572.6	(7%)	287.0	243.3	18%
Gross profit	256.5	315.8	(19%)	160.6	95.9	68%
GM%	48%	55%		56%	39%	
EBITDA – adjusted ²	165.3	206.5	(20%)	94.8	70.5	35%
Adjustments	(48.5)	17.7	nm	(1.0)	(47.5)	(98%)
EBITDA – reported	116.8	224.2	(48%)	93.8	23.0	307%
Net income – adjusted ²	60.3	90.2	(33%)	44.1	16.2	171%
Net income – reported	(133.9)	88.6	nm	40.3	(174.2)	nm
Cash flow from operations	121.5	(15.2)	nm	73.5	48.0	53%

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

2. Adjustments to FY18 EBITDA include \$17.3m abnormal stock adjustments, \$13.3m abnormal Doryx returns, \$16.3 restructuring charge, \$0.9m to remove HedgePath Pharmaceuticals (HPPI) losses and the fair value restatement of HPPI warrants and \$0.7m of legal costs associated with drug pricing investigations and related litigation. Net income also excludes \$184.4m intangible asset impairments, US tax rate change and the tax effect of those items.

"The strategic investments in additional manufacturing capability and capacity were completed during the year and are already delivering benefits to the Group with improved margins for the products transferred in-house and the continued strong growth of Metrics Contract Services, now able to offer clients a comprehensive 'concept to commercialisation' solution under one FDA site



registration. Metrics Contract Services has delivered three consecutive years of double digit revenue growth in USD and recently received revenues from its first long-term commercial manufacturing contract."

"The Company invested \$44m in research and development, focusing on first-to-market and complex generic projects and advancing its pipeline of specialty brands. Pleasingly, the Company filed eight products with the FDA including the NDA for its SUBA-Itraconazole anti-fungal capsule. The filed pipeline with the FDA is the strongest in the Company's history with 15 products targeting markets with combined sales greater than US\$2.5b¹, with several potential first-to-market product opportunities which are expected to drive growth in the near term."

Operating Performance

Generic Products Division (GPD)

The GPD operating segment's sales were \$385.7m, down 8% on FY17 and gross profit was \$177.4m. Dofetilide, liothyronine, doxycycline, budesonide and carbidopa/levodopa were the key drivers of growth, offset by pricing pressures largely focused in the oral contraceptive portfolio.

In US dollar terms, sales were US\$299.0m down 5% on pcp with the 2HFY18 sales and gross margin up 12% and 78% respectively on the 1HFY18 and up 7% and 26% on the 2HFY17.

The generic portfolio performed strongly in the second half driven by six new product launches, normalised levels of stock obsolescence, improving business mix and cost savings from the transfer of manufacturing of select products into Greenville and Salisbury from third party manufacturers.

The Company expects to achieve further cost savings from future product transfers through accessing lower manufacturing costs at new contract manufacturers or active pharmaceutical ingredient suppliers, or gains from overhead recovery throughput benefits across the internal manufacturing network.

The abnormal one-off stock adjustments in the first half did not repeat in the 2HFY18 and the division reported stock obsolescence of less than 3% of sales.

Specialty Brands Division (SBD)

The SBD operating segment's sales were \$44.7m and gross profit was \$37.5m. In US dollar terms, SBD's sales were US\$34.7m with 2HFY18 sales up 121% on 1HFY18. The 1HFY18 results were impacted by US\$9.7m of abnormal Doryx returns which did not recur in the second half. Adjusting for Doryx returns, SBD sales were up 17% in 2HFY18 on the 1HFY18 driven by the two foam products, Fabior and Sorilux.

The expansion of the sales team to 114 specialty sales representatives in the first half has helped drive growth in the underlying demand of these products, as measured by dispensed prescriptions.

Prescriptions for Fabior were up 30% and Sorilux up 75% in the 2HFY18 versus the 1HFY18 and the total number of prescribers writing these products has been growing consistently since

¹ IQVIA MAT Sales Jun 2018



November 2017. The Company also sees the breadth of prescribing growing, as the number of prescriptions per return writer has also improved for both products since the expansion of the sales team in December 2017. The Company is confident it can further build market share for these products and support any future brands that are added to the dermatology portfolio.

Metrics Contract Services (MCS)

The MCS operating segment's sales were \$63.1m, up 9% on FY17 and gross profit was \$33.7m up 5% on FY17. In US dollar terms, sales were up 12% to US\$48.9m with MCS now delivering three years of double digit annual revenue growth, well ahead of CDMO² industry growth rates of 6-7%. The strong performance reflects MCS's strong reputation in the marketplace and the strategic investments made in Greenville over the last three years in new manufacturing capacity and capability which has enabled MCS to attract new business as well as create a pipeline of potential commercial contract manufacturing business.

The new Greenville solid oral dose facility officially opened in April which quadruples the Company's capacity for oral solid-dose pharmaceuticals in the US and introduces new capacity to manufacture potent compounds and new capability to manufacture modified-release bead/pellet products. The new facility also allows MCS to repurpose its former manufacturing facility to expand pre-commercial product development capacity with the creation of 10+ new processing rooms and expanded laboratories to serve MCS clients.

In May, a full service MCS client gained FDA approval for its NDA for a new prostate cancer drug which lists MCS as the drug product manufacturer. MCS supported all aspects of drug product formulation, method development, testing, clinical trials manufacturing and now commercial manufacture.

Over time, MCS expects to transition from a predominately project-based revenue stream to include a mix of recurring revenue from commercial manufacturing. In the last two years, MCS has supported registration batch manufacture for six products, with another ten already scheduled over the next two years. In addition, the business has 20 potential commercial manufacturing opportunities under discussion with peak aggregate annual unit demand of 250 million doses.

Mayne Pharma International (MPI)

The MPI operating segment's sales were \$36.8m up 7% on FY17 and gross profit was \$8.0m up 18% on FY17. Australian sales benefited from increased sales of aspirin, injectables, itraconazole and oxycodone. New product launches of Monurol[®] (fosfomycin trometamol) and Urorec[®] (silodosin) also contributed to the result. Rest of world sales grew 11% driven by Kapanol[®] (morphine sulfate) in Canada and SUBA-itraconazole. The stronger gross margin reflects improving business mix and renegotiation of supply agreements.

Pipeline

Mayne Pharma's development pipeline includes over 30 products targeting US markets with sales greater than US\$5bn³. The Company has 15 products pending approval at the FDA with a total market value of more than US\$2.5bn³. During the year, the Company filed eight products with the FDA including its NDA for SUBA-itraconazole capsule, received FDA approval for five generic

² Contract Development and Manufacturing Organisation

³ IQVIA MAT Sales Jun 2018



products and launched six generic products in the US. In Australia, the Company launched two specialty brands products.

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.

In Australia, SUBA-Itraconazole continues to perform well capturing 34% volume share of the itraconazole market⁴. Since launch, the overall itraconazole market has grown 18% annually benefiting from increasing diagnosis and treatment of fungal conditions as well as growing its share of the anti-fungal market⁴. Over the next year, the Company expects to launch SUBA-itraconazole in another six countries, including the US assuming the product is approved following the acceptance of the NDA in April 2018. If approved, this product will be commercialised through the Specialty Brands business unit calling on a range of primarily hospital-based specialists that treat patients with, or at risk of certain fungal infections. The Company expects to have the new sales team in place during CY2019.

The SUBA-Itraconazole cancer program being progressed by HedgePath Pharmaceuticals, Inc., a partly owned subsidiary (53.5% ownership) of Mayne Pharma, has an upcoming pre NDA meeting with the FDA in anticipation of a potential filing of its NDA later this year. HPPi's primary goal is to bring to market SUBA-Itraconazole as a treatment for Basal Cell Carcinoma in patients with Basal Cell Carcinoma Nevus Syndrome (BCCNS, also known as Gorlin Syndrome).

In terms of the generic pipeline, the Company continues to invest in the development of new products focusing on first-to-market, difficult to develop and manufacture products utilising advanced drug delivery systems and potent handling capabilities. The Company has seven generic products pending approval with no generic equivalents today targeting markets with sales of more than US\$2.0b⁵. The most significant of these is the Company's filing of generic NuvaRing, an intra vaginal hormonal contraceptive delivery device. Merck's NuvaRing had total US sales of US\$890m⁵.

Debt and Cash Flow

The Company ended the year with net debt of \$287m down \$16.4m from 31 December 2017. Cash on hand at 30 June 2018 was \$87.3m and the Company had borrowings of \$374.1m.

The Company achieved positive net operating cash flow after interest, tax, working capital and one-off items of \$121.5m after an outflow of \$15.2m in the prior year. The 2HFY18 net operating cashflow was up 53% on the 1HFY18.

Significant cash flow items during the period include \$54.2m in capital expenditure, \$43.5m payments for product development (expensed and capitalised), \$23.4m in earn-out payments, \$8.0m in net tax payments, \$15.0m in net interest payments and a \$4.8m working capital release.

⁴ IQVIA MAT units (tablet/capsules), Dec 2017

⁵ IQVIA MAT Sales Jun 2018



Outlook

The US pharmaceutical market continues to be extremely dynamic with potential government policy changes and ongoing channel shifts through vertical integration of the supply chain across wholesalers, retailers, pharmaceutical benefit managers and insurers. In addition, a number of major participants such as Teva, Mylan, Perrigo and Novartis/Sandoz have announced plans to complete strategic reviews, restructure their operations or divest certain US assets.

The Company views this dynamic environment favourably and remains focused on executing on its key strategic initiatives which include diversifying channels to market, growing share of marketed products, extracting product cost savings from optimising the supply chain network, bringing new products to market and further business development activity.

The Company will continue to maintain a conservatively structured balance sheet and drive organic growth and pursue shareholder value accretive business development opportunities, such as the recently completed acquisition of generic Efudex[®], while improving profitability and cashflow through an efficient operating model.

The outlook is positive across the Group with a more stabilised retail generic pricing environment, an established specialty sales platform in US, anticipated new product launches, the acquisition of generic Efudex, portfolio optimisation and the pipeline of committed contract service business expected to be key drivers of near and long-term growth.

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ASX Announcement

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 potent compounds, controlled substances, modified release products and inherently unstable compounds.

NuvaRing® and Efudex® are registered trademarks of third parties.