



23 February 2018

MAYNE PHARMA REPORTS 2018 HALF YEAR PERFORMANCE

- Revenue of \$243.3m, a decrease of 17% on 1HFY17
- Adjusted EBITDA of \$70.2m, down 36% on 1HFY17
- Reported EBITDA of \$23.0m, down 82% on 1HFY17
- Reported net loss after tax of \$174.2m driven by asset impairments, abnormal Doryx® returns and stock obsolescence, restructuring expenses and restatement of deferred tax assets and liabilities following the US tax rate change
- Positive operating cash flow of \$48.0m
- Significantly improved trading in 2QFY18 which has strengthened further into January
- US generic market appears to be stabilising and competitor disruptions creating opportunities
- Expanded Specialty Brands team to 120 sales representatives to drive growth of Fabior®, Sorilux® and Doryx® MPC
- New Greenville manufacturing facility to commence production in the next month, enhancing internal capabilities and improving margins for third party transferred products
- Business positioned for a stronger second half driven by stabilising generic market, new product launches, expanded dermatology sales team, contract services committed business pipeline and cost benefits from the restructure

Commenting on the half year result, Mayne Pharma's CEO, Mr Scott Richards said, "While our first half results reflect a challenging generic environment and a disappointing Specialty Brands result, Mayne Pharma continues to have a number of strong performing business segments, products and pipeline opportunities. Metrics Contract Services, Mayne Pharma International, dofetilide capsules, doxycycline hyclate IR tablets and budesonide capsules were key contributors in the half versus the prior corresponding period. The pipeline is expected to drive growth in future periods driven by key launches including generic NuvaRing® and our patented formulation of SUBA®-Itraconazole as an anti-fungal in the United States."

Summary of results¹

\$m	1HFY18	1HFY17 pcp	Change on pcp	
			\$m	%
Revenue	243.3	294.8	(51.5)	(17%)
Gross profit	95.9	171.2	(75.3)	(44%)
GM%	39%	58%		
EBITDA – adjusted ²	70.2	109.9	(39.7)	(36%)
EBITDA – reported	23.0	129.2	(106.2)	(82%)
Net income / (loss) - adjusted	16.0	59.5	(43.5)	(73%)
Net income / (loss) - reported	(174.2)	72.7	(256.9)	Nm

1. Earnings attributable to members of the Company.

2. Adjustments to EBITDA in 1HFY18 include \$17.3m abnormal stock adjustments, \$13.3m abnormal Doryx returns, \$14.0m restructuring charge and \$2.6m to remove HedgePath Pharmaceuticals Inc. (HPPI) losses and the fair value restatement of HPPI warrants.

As foreshadowed at the AGM in November 2017, the Company completed a detailed review of the Company's intangible assets taking into account the current and projected market dynamics. This has resulted in a non-cash (pre-tax) charge of \$184m relating largely to the intangible asset

impairment of the acquired Teva portfolio assets. In addition, the reported results have been impacted by a number of abnormal one-off items including \$17m of extraordinary stock obsolescence charges and sell through of short dated stock below cost, \$13m of abnormal Doryx returns and sample write-offs, and a \$14m restructuring charge to reduce the cost base - covering the cancellation of employee loan shares, renegotiation of supply chain contracts and other expense management initiatives. The ongoing restructure of the cost base across FY18 is expected to drive benefits of up to \$7m on an annual basis.

During the period, the Tax Cuts and Jobs Act was signed into US legislation which resulted in the corporate federal tax rate declining from 35% to 21% from 1 January 2018. Reported NPAT has been impacted by a one-off charge to income tax expense of \$14m which reflects the restatement of deferred tax assets and liabilities.

Adjusting for these one-off items, group revenue would have been down 13% on pcp, gross profit margin would have been 50% and adjusted EBITDA was \$70.2m down 36%.

The Company remains committed to growing its core business segments by investing in both internal and external product development opportunities. During the half, the Company invested \$63m in its facilities and product pipeline with \$40m primarily spent on the expansion programs at Greenville and Salisbury, in addition to \$23m on research and development. The solid oral dose manufacturing facility in Greenville is almost complete and the Company is in the process of transferring in house 8 acquired Teva products which are currently outsourced. This will increase the economic benefit that flows to Mayne Pharma as well as introduce downstream commercial manufacturing services to Metrics Contract Services.

Operating Performance

Generic Products Division (GPD)

The GPD operating segment's sales were \$180.9m, down 19% on 1HFY17 and gross profit was \$63.6m.

In US dollar terms, sales were US\$141m down 16% on pcp and down 5% on 2HFY17. Price deflation pressures have begun to abate with the generic portfolio experiencing low single digit deflation in 1HFY18 versus 2HFY17. Dofetilide remains the largest generic product and grew 19% on pcp to US\$33m. Doxycycline, budesonide and carbidopa/levodopa grew strongly, offset by continued competitiveness across the oral contraceptive portfolio.

Gross profit margin was impacted by \$17m of one-off abnormal stock adjustments including stock obsolescence, writedowns and sell through of short dated stock below cost to mitigate the full obsolescence risk as well as \$3m of restructuring costs to improve the cost base. Adjusting for these one-off items, the generic gross profit margin would have been 46%, instead of 35%.

The Company is focused on expanding channels to market, extracting cost savings from optimising the supply network, aggressively pursuing new opportunities through launching products, portfolio optimisation and business development activity. Since October 2017, GPD performance has significantly strengthened with 2QFY18 sales up 30% on 1QFY18 and January 2018 sales were up 13% on the monthly average in 2QFY18.



Cost savings from the transfer of acquired Teva products into Greenville, Salisbury or alternate contract manufacturing organisations continue to progress. The Company expects to achieve US\$12m of cost savings on an annual basis from these transfers through accessing lower manufacturing costs at the new network of contract manufacturers or gains from overhead recovery throughout benefits across the internal manufacturing network.

Metrics Contract Services (MCS)

The MCS operating segment's sales were \$29.7m, up 6% on 1HFY17 and gross profit was \$15.8m, up 2% on pcp. In US dollar terms, MCS' sales were up 9% on pcp to US\$23m with gross margins of 53%.

The opening of the new Greenville commercial manufacturing facility is expected to transition MCS from a project based revenue stream to include a mix of ongoing recurring revenue streams related to commercial manufacturing. MCS supported registration batch manufacture for 3 programs over the half in addition to supporting its first client complete manufacturing process validation for approval and launch of its product in 2018. The pipeline of commercial manufacturing opportunities continues to grow, and the Company expects to receive its first commercial manufacturing revenues in the 2HFY18.

Specialty Brands Division (SBD)

The SBD operating segment's sales were \$13.8m and gross profit was \$11.6m. These results were negatively impacted by \$12.4m of Doryx returns which related to the loss of exclusivity on legacy Doryx 50mg and 200mg tablets in May 2016.

Excluding Doryx returns, SBD adjusted revenue would have been \$26m consistent with pcp and gross margin would have been 91%. The 1QFY18 sales were impacted due to seasonality of acne products through the summer months, a 1 July price rise on Fabior which drove strong sales in June 2017 and heightened loyalty card costs due to a one-off promotion offer. The 2QFY18 adjusted revenues rebounded and grew 49% on the 1QFY18.

Towards the end of the half, the Company doubled the sales team to 120 sales representatives and the impact of this investment is yet to be seen in the financial results. In the latest week of prescription data, which measures underlying demand of these products, Doryx MPC, Fabior and Sorilux prescriptions were up 12%, 17% and 86% respectively on the baseline prior to the expansion of the sales team¹.

Mayne Pharma International (MPI)

The MPI operating segment's sales were \$18.8m, up 8% and gross profit was \$5.0m, up 31%. Australian sales grew strongly driven by aspirin, itraconazole and injectables and international sales benefited from the renegotiation of supply agreements.

Urorec® capsules, indicated for the relief of lower urinary tract symptoms associated with benign prostatic hyperplasia in adult men and Monurol® granules, used to treat urinary tract infections were launched during the period, also contributing to the growth.

¹ Based on IQVIA, weekly TRx as at 9 February 2018 versus baseline prior to expansion of the second sales team in 1QFY18.



Pipeline

The Company continues its commitment to advancing its product pipeline. In 1HFY18 research and development spend was \$23.2m of which more than 80% was directed towards US generic programs that leverage the Company's drug delivery platform technologies.

Mayne Pharma's US development pipeline consists of 30+ products targeting US markets with sales greater than US\$5bn² of which 13 products are pending approval at the FDA with total market sales of more than US\$1bn². During the half, the Company received FDA approval for three generic products – doxycycline monohydrate capsules, clozapine tablets (50 mg and 200 mg) and amiodarone tablets; filed three products with the FDA and added two products into development.

SUBA-Itraconazole

In the 2HFY18, the Company expects to submit a New Drug Application to the FDA for SUBA-Itraconazole capsules to treat certain fungal infections and is targeting commercial launch in FY19, through a dedicated infectious disease sales team. SUBA-Itraconazole is a patented formulation which has improved absorption and significantly reduced variability in blood levels achieved compared to Sporanox® (the originator formulation). In Australia and Spain, where the product has been available for several years, it has captured more than 30% and 25% market share respectively of itraconazole prescriptions. The US addressable market is expected to be US\$200m per annum based on target pricing and the systemic infection patient population.

In January 2018, the Company invested a further US\$2.4m in HedgePath Pharmaceuticals Inc. (HPPI), a partly owned subsidiary of Mayne Pharma to progress the development of itraconazole as a potential treatment for cancer. HPPI has completed enrolment of its 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 and continues to report positive results from its open label trial. In the latest data set they have measured the response of 477 individual target tumours, with 54% exhibiting a 30% or greater reduction in size since dosing began and 28% disappearing completely. Approximately 60% of lesions have continued to respond during ongoing treatment with a duration of response currently exceeding one year. The US addressable market is estimated at US\$300m per annum based on an assessment of current healthcare costs to treat this patient population. Mayne Pharma is also exploring broader oncology indications including prostate and ovarian cancer.

Net Debt and Cash Flow

The Company ended the year with net debt of \$303m. Cash on hand at 31 December 2017 was \$56m and the Company had borrowings of \$359m.

The Company achieved positive net operating cash flow after interest, tax, working capital and one-off items of \$48.0m. Significant cash flow items during the period include \$39.5m in capital expenditure, \$23.2m payments for product development (expensed and capitalised), \$17.8m in earn-out payments, \$6.8m in net tax payments, \$6.9m in net interest and a \$8.8m working capital release.

² IQVIA, MAT sales, Dec 2017



Outlook

With the positive trading momentum over the last three months, the Group is well positioned for a stronger second half, driven by the stabilising generic market, new product launches, increased share penetration of on market products, portfolio optimisation and expanding distribution channels. SBD is poised to benefit from the expansion of the dermatology sales team which was completed in December 2017. MCS key performance indicators are trending favourably for growth over the remainder of the financial year with committed business up 30% from twelve months ago. MPI is expected to benefit following the launch of Monurol and Urorec in 1HFY18.

With improving cash generation, the Company will continue to invest in both internal and external growth initiatives that can broaden the portfolio, improve profitability and create long-term shareholder value.

For further information contact:

Nick Freeman +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.