ASX Announcement

21 February 2020

MAYNE PHARMA REPORTS 1HFY20 RESULTS

- Reported revenues of $227.2m, down 17% on 1HFY19
- Reported EBITDA of $34.6m, a decrease of 47% on 1HFY19
- Underlying EBITDA of $47.4m, a decrease of 42% on 1HFY19
- Reported net loss after tax of $17.5m driven by lower earnings and restructuring expenses
- Net operating cashflow of $46.2m down 14% on 1HFY19
- Licensed novel oral contraceptive E4/DRSP in the US
- Generic NUVARING® complete response letter submitted to the US Food and Drug Administration (FDA) with launch anticipated in CY20
- Filed three generic products with the FDA including a potential first-to-market women's health product
- Significant spend base reduction of $20m (annualised) to further right size organisation and optimise global infrastructure

Mayne Pharma's CEO, Mr Scott Richards said, "As previously foreshadowed at the 2019 Annual General Meeting, performance in the 1HFY20 has been disappointing due to the competition we have faced on our key generic products. The US generic market continues to be challenging with aggressive contracting behaviour driving heightened levels of price deflation, particularly in markets where there are multiple generic players. Given these dynamics, the Company has executed meaningful reductions in its cost base during the period with operating expenses declining by $10m versus 2HFY19 on a constant currency basis. We have also rationalised our generic portfolio, discontinuing several unprofitable products, and will continue to extract further meaningful cost reductions in future periods. Pleasingly our Specialty Brands business, which had a soft 1QFY20, rebounded in the 2QFY20 with sales up 50% and Metrics Contract Services delivered another solid result."

Summary of results[1]

				Change on pcp	
$m	1HFY20	2HFY19	1HFY19	$m	%
Reported revenue	227.2	250.8	274.4	(47.2)	(17%)
Reported gross profit	105.7	129.5	160.4	(54.7)	(34%)
GM%	*47%*	*52%*	*58%*		
EBITDA – reported	34.6	46.2	65.4	(30.8)	(47%)
EBITDA – underlying[2]	47.4	49.7	81.2	(33.8)	(42%)
Net income / (loss) - reported	(17.5)	(283.6)	2.6	(20.1)	nm
Cash flow from operations	46.2	53.1	53.5	(7.3)	(14%)

1. Earnings attributable to members of the Company with exception of cash flow which is consolidated.
2. Adjustments to EBITDA in 1HFY20 include $10.8m restructuring charge, $6.4m credit arising from the decrease in fair value of earn-out liabilities, $5.5m of abnormal gross to net adjustments, $1.2m of legal costs associated with drug pricing litigation and $1.4m to remove Inhibitor Therapeutics, Inc. (INTI) losses attributable to members and restatement of the value of Mayne Pharma's INTI warrants and $0.3m of E4/DRSP related costs.

"Whilst performance over the last few years has been volatile, the Company's medium term outlook has improved significantly over the last year following the approval and launch of TOLSURA® and the licensing of the novel oral contraceptive E4/DRSP, which has the potential to transform our business and growth trajectory. The Company continues to have many near term opportunities for growth including the potential launch of generic NUVARING® this calendar year and a number

of other potential high impact generic launches, new commercial manufacturing revenues from MCS client NDA launches across calendar 2020 and further cost savings from realigning the supply base."

"The strategic priority for Mayne Pharma is to complete the repositioning of the business into sustainable categories and therapeutic areas, build a leadership position in women's health and dermatology and invest in and grow our contract service business. In dermatology, we have recently launched three products - generic LOCOID® lotion, generic CORDRAN® ointment and generic TRIANEX® ointment to leverage the established sales and distribution capability. In women's health, we have the upcoming planned launches of generic NUVARING and E4/DRSP and continue to optimise the on market branded generic oral contraceptive portfolio. In Contract Services, we have expanded our scientific workforce dedicated to third party work both in Australia and the US to support the pipeline of committed business as well as attract new clients and projects."

Operating Performance

Specialty Brands Division (SBD)

The SBD operating segment's sales were $44.9m, up 4% on the prior corresponding period (pcp) and gross profit was $38.4m up 1% on pcp. In US dollar terms, SBD's sales were US$30.8m, down 2% on 1HFY19.

SORILUX® and DORYX® sales were down on the prior period impacted by new competitor launches, offset by growth in FABIOR®, LEXETTE® and TOLSURA. SBD performance strengthened in the 2QFY20 with sales up 50% on 1QFY20 benefiting from a rebound in DORYX and SORILUX and continued growth in LEXETTE. During 1HFY20, the Company restructured the sales team which is expected to deliver US$6m of annualised savings and improved profitability going forward.

The launch of TOLSURA in January 2019 has allowed Mayne Pharma to establish a new hospital based commercial platform calling on infectious disease and pulmonology physicians. TOLSURA is now approved on eight major hospital network formularies, with a further 18 under active review. New patients and prescription volumes are steadily increasing quarter on quarter.

Generic Products Division (GPD)

The GPD operating segment's sales were $124.5m, down 29% on 1HFY19 and gross profit was $45.5m, down 55% on pcp. In US dollar terms, sales were US$85.3m down 33% on 1HFY19.

GPD performance was impacted by intense competition on the key products including liothyronine, dofetilide and butalbital, along with $5.5m of stock writedowns due to the discontinuation of unprofitable generic products and $5.5m of abnormal gross-to-net charges from returns and government fees. Adjusting gross margin for the stock writedowns and gross to net charges, the generic gross margin would have been 44%, instead of 37%.

Metrics Contract Services (Metrics or MCS)

The MCS operating segment's sales were $38.4m, up 13% on 1HFY19 and gross profit was $17.5m up 6% on pcp. In US dollar terms, sales were up 7% on pcp to US$26.3m.

Metrics benefited from additional analytical services and formulation development revenues. Metrics has now signed global commercial manufacturing supply agreements with two top 10 global pharma companies to manufacture FDA approved oncology medications. MCS supported both companies with drug product formulation, analytical method development, clinical trial supplies and now commercial manufacturing. Over time, MCS is expected to transition from a predominantly project-based revenue stream to include a mix of ongoing recurring revenue from commercial manufacturing. This new commercial business reflects the capital investments made in Greenville, North Carolina to build a new solid oral dose manufacturing facility which opened in 2018. Metrics is expected to have five commercial manufacturing clients by the end of FY20.

Metrics has a strong track record of growth supporting around 100 clients each year to develop, test and commercialise innovative drugs. The market for contract development and manufacturing services remains highly attractive with growth outpacing the broader pharmaceutical industry due to the increase in outsourcing activity by pharma companies as they rationalise manufacturing sites and the growth in the number of molecules in clinical trials. Metrics remains one of a few US based potent solid oral dose CDMOs for early stage development through to commercialisation from a single contiguous site.

Mayne Pharma International (MPI)

The MPI operating segment's sales were $19.3m down 9% on 1HFY19 and gross profit was $4.3m down 26% on pcp. The softer sales and gross profit performance reflect the end of a 20-year KAPANOL® royalty income in Japan and lower margin commercial manufacturing revenues. MPI added two further contract service projects leveraging Salisbury's topical development capability and grew its sales across the portfolio of Specialty Products marketed in Australia including MONUROL®, UROREC® and LOZANOC®.

Pipeline

Over the last year, the Company has streamlined generic drug development, abandoned non-viable projects and focused portfolio selection on opportunities that align with core therapeutic categories. The Company's network of external development partners has strengthened as demonstrated by the licensing of a number of topical products from Encube Ethicals Pvt Ltd and Teligent, Inc. Today, the Company's generic pipeline includes 12 products pending at the FDA. We hope to bring several products to market across calendar 2020 including generic NUVARING, following submission of the complete response letter to the FDA in December 2019.

In 1HFY20, gross research and development spend was $20.2m of which ~70% was directed to the core therapeutic categories of dermatology, women's health and infectious disease. The Company continues to direct its internal R&D spend to its earlier stage brand programs including two key projects in phase 2 and phase 3 development. A global phase 2 trial has commenced in 120 patients with lamellar ichthyosis, an orphan disease causing severe skin scaling. There are no treatments approved by the FDA for moderate or severe subtypes of this disease. The Company also continues to progress the SUBA-itraconazole program as a potential treatment for Basal Cell

Carcinoma Nevus Syndrome (BCCNS or Gorlin Syndrome). A global phase 3 trial is expected to commence in CY20 in moderate to severe BCCNS patients.

E4/DRSP oral contraceptive

The Company's most significant late stage program is the novel oral contraceptive E4/DRSP, which has completed two phase 3 clinical studies in more than 4,400 patients with positive top line results for the efficacy and safety endpoints and achieved secondary endpoints including good bleeding profile, cycle control and tolerability. E4/DRSP is expected to be filed with the FDA in the 2HFY20, with potential launch in the first half of calendar 2021. This product will compete in the short-acting US contraceptive market in which more than 10 million American women use combination (estrogen + progestin) oral pills, patches or vaginal rings each day. This combined hormonal contraceptive market is valued at US$4b with the top two brands being NUVARING contraceptive ring with US$960m in sales and LO LOESTRIN® FE with US$860m in sales, according to IQVIA.

Debt and Cash Flow

The Company achieved positive net operating cash flow after interest, tax and working capital of $46.2m, down 14% on the prior period. Significant cash flow items during the period include $27.1m in payments for intangible assets and earnout payments, $18.6m in gross R&D spend, $12.2m decrease in working capital and $6.9m in net interest payments.

The Company had gross debt of $388.7m, cash on hand of $98.5m and retains significant buffer within the bank covenants, with leverage at 2.5x and shareholders' funds of $1.1b.

Outlook

Mayne Pharma has a clear strategy for growth which centres on repositioning the business into more sustainable categories and therapeutic areas such as dermatology, women's health, infectious disease and contract services. The successful commercialisation of E4/DRSP, generic NUVARING and TOLSURA will be the key drivers of this transformation and should lead to more durable earnings and cashflow over time.

In addition, contract services is expected to benefit from expansion of the technical team and the growing pipeline of committed commercial manufacturing business and specialty products is expected to benefit from the recent dermatology sales force restructuring driving a more profitable business model.

The Company will also continue to tightly manage its expense base, achieve greater operating efficiencies in the manufacturing network and optimise the supply base to realise further cost savings.

Further information

Additional details about Mayne Pharma's results are included in the Company's 4D statement, investor presentation slides and webcast, all of which can be found on Mayne Pharma's website www.maynepharma.com. For further information please contact:

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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.

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