

14<sup>th</sup> May 2019

## MAYNE PHARMA MARKET UPDATE

- Mayne Pharma 2H19 sales impacted by additional competition on key generic products and generic market trading pressures
- Company expects stronger FY20 results driven by recent specialty brand launches of TOLSURA® and LEXETTE™, growth of the generic and proprietary dermatology and women's health portfolios, potential market supply disruptions and the pipeline of committed Metrics Contract Services business
- A detailed review of the carrying value of generic acquired and development intangible assets will be undertaken at 30 June 2019

### Trading update and Outlook

Mayne Pharma Group Limited (ASX: MYX) today provides an unaudited trading update for the 10 months ended 30 April 2019.

A\$million	YTD Apr 19	YTD Apr 18	Change %	1H19	1H18	Change %	Jan - Apr 19 (4 months)	Jan - Apr 18 (4 months)	Change %
Specialty Brands	71.3	32.1	122%	43.3	13.8	214%	28.0	18.3	53%
Contract Services	58.8	50.3	17%	33.9	29.7	14%	24.9	20.6	21%
Generic Products	264.8	311.0	(15%)	175.9	180.9	(3%)	88.9	130.1	(32%)
MPI	33.6	30.2	11%	21.3	18.8	13%	12.3	11.4	8%
<b>Reported revenue</b>	<b>428.5</b>	<b>423.6</b>	<b>1%</b>	<b>274.4</b>	<b>243.2</b>	<b>13%</b>	<b>154.1</b>	<b>180.4</b>	<b>(15%)</b>
<b>Reported gross profit</b>	<b>239.0</b>	<b>194.3</b>	<b>23%</b>	<b>160.4</b>	<b>95.9</b>	<b>67%</b>	<b>78.6</b>	<b>98.4</b>	<b>(20%)</b>
<b>Group gross profit %</b>	<b>56%</b>	<b>46%</b>		<b>58%</b>	<b>39%</b>		<b>51%</b>	<b>55%</b>	
Average AUD/USD FX rate									
	0.7194	0.7753		0.7241	0.7792				

Mayne Pharma CEO, Mr Scott Richards said, "As foreshadowed at our half year results in February, our generic business has faced a challenging start to calendar 2019 driven by competitive pressure on our key products including liothyronine and dofetilide. We have also faced typical wholesaler destocking in the retail channel in the first calendar quarter, one-off failure-to-supply penalties emanating principally from products supplied by third party manufacturers, together with shelf stock adjustments resulting from price changes on some products. Pleasingly, all other segments have demonstrated good growth in the first four months of the half with Specialty Brands up 53%, Metrics Contract Services up 21% and Mayne Pharma International up 8% on the prior corresponding period (pcp)."

"Whilst recent trading reflects a challenging generic environment, the Company expects the 4QFY19 to be stronger driven by a rebound in Generic Products, combined with ongoing growth in Specialty Brands, Metrics Contract Services and Mayne Pharma International."

"A positive by-product of the current generic environment is an increase in opportunities to capture value from supply disruptions and competitors exiting certain product markets. We continue to see a number of these opportunities ahead of us, some of which are temporary and others which are permanent market exits by competitors providing longer term stability to our generic business."

"In FY20, the Company expects stronger results driven by recent specialty brand launches of TOLSURA and LEXETTE, growth of the generic and proprietary dermatology and women's health portfolios, improved retail generic performance and delivery on the pipeline of committed Metrics Contract Services business. Various initiatives at the Greenville site are also expected to drive greater operational efficiencies and improved financial performance across FY20 and beyond. In addition, the Company has a number of generic products pending approval at the FDA and expects to commercialise several of these over the coming year with the launch of generic NUVARING® expected to occur in CY20. The Company has recently executed two licence agreements commencing in FY20 to participate in two new product markets with no generic equivalents today with combined IQVIA sales of US\$150m<sup>1</sup>."

## Strategy Update – Providing Valued Solutions to Patients and Prescribers

Mayne Pharma's commercial strategy is to deliver value to patients and prescribers by providing the right products, both generic and branded, via an efficient distribution model that aims to ensure patients can access the products prescribed to them in a seamless and affordable manner. Our strategic priority is to continue to expand our 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 over the last 12 to 18 months.

The Mayne Pharma Board has recently reviewed the Company's strategic direction and key operational priorities to deliver long-term growth. Whilst we have challenges and opportunities in the generics sector, the Board expects that generics will remain a substantial part of the Mayne Pharma business for the foreseeable future. The Board also supports continued focus on contract services, repositioning of the products businesses towards specialty branded products and sustainable generic portfolios/channels and related distribution activities, to capitalise on the Company's innovative business model and established commercial capabilities. The ultimate aim of this shift is to produce more durable earnings streams with less volatility to maximise long-term returns for our shareholders.

In terms of dermatology, the Company continues to grow its on-market branded and generic business through improved sales force effectiveness, internal product development, in-licensing and acquisition. The launch of LEXETTE foam in February 2019 is expected to be a key growth driver in the coming year leveraging existing commercial infrastructure and participating in the US\$600m<sup>1</sup> topical corticosteroid market, which is the cornerstone treatment for plaque psoriasis patients. The Company is also in active discussions with a number of third parties around potential product collaborations to leverage its dermatology sales and distribution capability.

Mayne Pharma's women's health portfolio covers approximately 50% of obstetrician/gynaecologist (OB/GYN) prescription needs in oral contraception and the pipeline includes three further products including the largest contraceptive product sold in the US – generic NUVARING, which is pending at the FDA. The breadth of this portfolio has enabled Mayne Pharma to consider alternate distribution approaches that would be valued by OB/GYN physicians and their patients. The Company expects that FY20 will be a pivotal year in the development of its distribution model and will seek to add new products to the women's health portfolio, including a complementary brand to support investment in a national sales force. Lastly, over the next couple of years the Company expects to further optimise the cost base of its women's health portfolio through

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<sup>1</sup> IQVIA, Sales, March 2019

product transfers to new contract manufacturers to realise approximately US\$15m of annual cost savings based on current volumes. The majority of these savings are expected to be achieved in FY21.

The launch of TOLSURA in February this year has allowed Mayne Pharma to establish a new hospital channel commercial platform, with sales and account management personnel calling on infectious disease physicians and other healthcare professionals. Based on initial dialogue with prescribers, hospital formulary decision makers and managed care, the Company expects TOLSURA to be a strong growth product in FY20 and beyond. Further, this newly established hospital platform has the potential to springboard Mayne Pharma into additional therapeutic categories through a mix of follow-on R&D investments and complementary product licensing activities.

Mayne Pharma's US retail generic business continues to face challenging market dynamics as a result of customer consolidation and additional competition from new generic launches. These dynamics continue to drive heightened levels of price deflation and pressure on trading terms which are leading to competitors withdrawing products, not launching recently approved products and restructuring their operations. In FY18, the US Food and Drug Administration (FDA) recorded its highest number of generic approvals but at the same time approximately only one-third of these products were launched due to, at least in part, the inability to generate a satisfactory economic return. Further, 606 generic products were withdrawn voluntarily by generic manufacturers in FY18, up from 214 withdrawals in FY17<sup>2</sup>.

In response to these pressures, Mayne Pharma is undertaking a number of actions to better align its generic business with retail market realities including further portfolio optimisation, abandoning non-viable development projects, and focusing its generic portfolio selection and product development expertise on opportunities that better align with core therapeutic channels, together with deepening external development networks to minimise execution risk and compress time-to-market. The Company also expects to take advantage, via selective licensing and distribution arrangements, of sustained sector headwinds that will likely result in an increasing number of generic products not being launched or being withdrawn from the market.

Given the prevailing US generic market conditions and outlook the Company will be performing a detailed review of the carrying value of its generic acquired and development intangible assets at the full year ending 30 June 2019, the impact of which cannot be quantified at this time. Any impairment would reset the balance sheet, improve reported profit in future periods and is consistent with many US generic peers who have also made impairments of their generic intangible assets over the last few years.

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<sup>2</sup> FDA Activities Report of the Generic Drug Program FY17 and FY18; IQVIA Global / US Generics and Biosimilars Trends, Issues and Outlook, Feb 2019



## Trading Update – First 4 months of CY19

### *Generic Products Division (GPD)*

Generic Products sales were \$89m in the first 4 months of CY19 down 32% on pcp driven by competitive pressure on key products. Dofetilide sales were down 84% on pcp to US\$3.7m and liothyronine sales were down 23% on pcp to US\$9.8m. Further, there were approximately US\$4m of one-off items that impacted the period including failure-to-supply penalties resulting largely from suppliers unable to deliver product on time and shelf stock adjustments resulting from price changes. Generic Products gross profit margin fell to 45% in the period down from 57% in the first half of FY19. Adjusting for these one-off items the gross profit margin would have been 51%.

### *Specialty Brands Division (SBD)*

Specialty Brands performed strongly in the first 4 months of CY19 with sales up 53% on pcp to \$28m. Growth has been across all key products with FABIOR® up 45%, SORILUX® up 4% and the DORYX® family up 39% in USD terms. The launch of LEXETTE in February has also contributed to the growth with total prescriptions exceeding 700 in the latest week of data<sup>3</sup>.

### *Metrics Contract Services (MCS)*

Metrics Contract Services reported revenue of \$25m in the first 4 months of CY19 up 21% on pcp driven by growing commercial manufacturing revenues and later stage formulation development work. The pipeline of commercial manufacturing opportunities remains attractive and with more than 20 commercial manufacturing quotes issued, MCS is expected to become an approved supplier in eight marketing applications over the coming year up from just one today.

### *Mayne Pharma International (MPI)*

Mayne Pharma International reported revenue of \$12m in the first 4 months of CY19 up 8% on pcp benefiting from growing sales of itraconazole globally and additional third party contract development and manufacturing services.

At a group level, revenue was \$154m in the first 4 months of CY19 down 15% on pcp and gross profit was \$79m down 20% on pcp. Cash on hand at 30 April 2019 of \$111m was \$15m higher than the position at 31 December 2018 after a US\$5m payment for the commercial launch of LEXETTE and the Company's bank debt remained consistent with the December 2018 balance. The Company continues to have significant head room under its bank covenants.

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<sup>3</sup> IQVIA weekly TRx, 3 May 2019



## ASX Announcement

### Investor Conference call

Mayne Pharma will host a conference call for shareholders and investors at 10.30am AEST on 14<sup>th</sup> May. Dial in details for the teleconference are below:

Conference ID:	9711770
Australia Toll Free:	1800 573 793
Australia Local:	+61 2 9193 3706
Hong Kong:	800 961 105
New Zealand:	0800 423 970
Singapore:	800 186 5107
United Kingdom:	0800 358 6377
United States/Canada:	866 548 4713
United States:	+1 323 794 2093

### For further information 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.*