



## ANNUAL GENERAL MEETING

RACV CLUB  
LEVEL 2, 501 BOURKE ST, MELBOURNE VIC 3000  
AT 10.00 AM ON 29 NOVEMBER, 2018

### CHAIRMAN'S ADDRESS

Good morning ladies and gentlemen, I'm Roger Corbett, the Chairman of our Company and I would like to welcome you all to the 2018 Mayne Pharma Annual General Meeting. As we have a quorum, I now declare the annual general meeting open.

Let me start by introducing the Board members, senior executives, and the Company's auditor.

Joining me at the front of the room are my fellow non-executive Directors: Bruce Mathieson, Ian Scholes, Ron Best, Professor Bruce Robinson, Nancy Dolan, Frank Condella and Pat Blake, our Chief Executive Officer, Scott Richards and our Group CFO and Company Secretary, Nick Freeman. I am very pleased to welcome Frank and Pat to their first Mayne Pharma AGM. Both Frank and Pat are US residents and have travelled from the US to be here. Frank brings more than 30 years of global pharmaceutical industry experience across brand, generic and contract service businesses and Pat brings more than 30 years of global healthcare industry experience including more than 20 years at McKesson Corporation one of the largest healthcare services and information technology companies globally and also our largest customer.

As many of you know Phil Hodges, the founder of Metrics will retire as a Director effective at the end of this Annual General Meeting. Phil joined the board six years ago and our Company has benefited greatly from Phil's entrepreneurship and the Metrics Inc acquisition which provided Mayne Pharma with the operating platform in the US. On behalf of the Board, we would like to thank Phil for his commitment and contribution to Mayne Pharma and in his honour we have decided to name the original Metrics facility the 'Hodges Building'.

Welcome also to Mr Ashley Butler, the Company's auditor for FY18 and other representatives of EY.

I'll now outline the procedure for today's meeting. There are three items of business on today's agenda:

1. I will present my Chairman's Report, then
2. Scott will provide an update on the trading performance; and then
3. We will go into the formal part of the meeting where we will vote on the resolutions outlined in the notice of meeting. We will then conclude the meeting.

**I will now move to the Chairman's report.**

FY18 has been another extraordinary period for our Company. This time last year we were facing a perfect storm in the US with extremely challenging market conditions driven by aggressive contracting behaviour from the major wholesaler / retail buying alliances as well as accelerated approvals through the US FDA. These issues drove a tough deflationary period in the US generic industry which impacted all players. Our US peers have reported weaker results, restructured their operations, divested assets in some cases and announced strategic reviews.

Compared to some of our industry peers, I am pleased to say Mayne Pharma has weathered this storm well. With a strong balance sheet, a diverse operating model that also includes specialty brands and contract services and an experienced management team to lead and execute on our strategy the Company reported a much stronger second half with revenue, earnings and cash flow all up significantly on the first half. The rapid turnaround in the second half reflects a rebound of Generic Products, improved performance of Specialty Brands and continued growth of Metrics Contract Services.

Moving to the actual results.

The Company reported revenue of \$530m, adjusted EBITDA of \$165m and reported net loss after tax of \$134m. These results were impacted by a number of one-off items including non-cash intangible asset impairment, extraordinary stock obsolescence, abnormal Doryx® returns, a restructuring charge to reduce the cost base and a charge to income tax expense resulting from the US corporate federal tax rate change. These one-off items largely impacted the results in the first half with minimal adjustments to reported earnings in the second half.

In terms of the segment performance, the Generic Product Division sales were \$386m, down 8% on FY17 and gross profit was \$177m. In US dollar terms, sales were US\$299m down 5% on pcp with the 2HFY18 sales and gross profit up 12% and 78% respectively on the 1HFY18. The second half benefited from six generic launches, cost savings from the transfer of manufacturing into Greenville and Salisbury from third party manufacturers, reduced stock obsolescence and improving business mix.

The Specialty Brands Division reported sales of \$45m and gross profit of \$38m which was down on the prior year impacted by abnormal Doryx returns in the first half. Pleasingly, the second half was much stronger with sales up 123% on the first half driven by Fabior® (tazarotene) foam and Sorilux® (calcipotrene) foam, which are the two products we launched in early 2017.

The Company is committed to building its dermatology franchise. Over the last year, the business has doubled its dermatology field sales team and invested in two further product acquisitions: on market, generic Efudex® (fluorouracil) cream used to treat actinic keratoses and a new specialty pipeline product Lexette™ (halobetasol) foam used to treat plaque psoriasis which is expected to launch in early 2019. We also have four dermatology pipeline assets under development.

Metrics Contract Services (Metrics) delivered another strong result with revenue up 9% to \$63m and gross profit up 5% to \$34m. In USD terms, sales were up 12% to US\$49m with Metrics now delivering three years of double-digit annual revenue growth in USD terms, well ahead of industry growth rates.

The performance of Metrics reflects its 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 Metrics to attract new business as well as create a pipeline of commercial contract manufacturing opportunities. Another key highlight of the year was the first commercial contract manufacturing revenues from a full-service Metrics client who received FDA approval for a new prostate cancer drug. Metrics has supported this client with formulation development and analytical services work over the last four years.

The final segment, Mayne Pharma International which includes our Australian operations and export sales grew revenue 7% to \$37m and gross profit increased 18% to \$8m. Australian sales benefited from two new product launches of Monurol® (Fosfomycin) granules and Urorec® (silodosin) capsules. Rest of world sales grew 11% driven by the Company's novel SUBA®-itraconazole and sustained release morphine sulphate.

The Company ended the year with cash of \$87m and outstanding borrowings of \$374m. The Company's gearing ratio was 2.1x on a net debt to EBITDA basis at 30 June 2018 and maintains considerable headroom under its bank covenants. Cash flow was significantly stronger this year with \$121m generated, after an outflow in the prior year and the Company generated free cash flow of \$33m after investing activities in the second half.

We made significant investments over the year to advance our product pipeline and expand our facilities.

In terms of our facilities, we completed on time the new solid oral dose facility in Greenville, North Carolina and the manufacturing expansion in Salisbury, South Australia. The Company has invested more than \$150m over the last three years to transform the manufacturing network and support the mid to long term growth we are forecasting across our product portfolio as well as offer commercial manufacturing to our Metrics clients. In the current year, the Company is expecting manufacturing volumes to grow substantially across our network driven by the additional volume coming in house from third party contract manufacturers.

These capex expansions have already begun to deliver benefits to the group with improved product margins, better customer service allowing us to respond quickly to market changes and the continued growth of Metrics Contract Services. Maintaining and investing in our facilities is also important for protecting our intellectual property assets and we will continue to invest in our pipeline in developing complex generic and specialty drugs that we look to commercialise around the world.

We are now nearing the end of the FDA review process for our SUBA-itraconazole anti-fungal product, which we expect to launch under the FDA conditionally approved brand name of Tolsura™. This product was developed in Adelaide using our novel SUBA technology which improves the bioavailability of poorly solubilised products and has been commercialised in Australia, Spain and Germany. Scott will talk more about this new specialty brand product shortly including the potential for repurposing SUBA-itraconazole in certain cancers.

In terms of R&D, the Company invested \$44m in FY18 to advance its product pipeline of generic and branded products and filed eight products with the FDA including the New Drug Application for the SUBA-itraconazole anti-fungal product. We had six generic launches in the US and two brand launches in Australia. Our R&D platform remains focused on developing both generic and specialty brand products. On the generic side we are focused on complex products with barriers to entry and on the brand side we are investing in a number of clinical programs to support our growing dermatology franchise.

I also wanted to give a brief update on the ongoing US Department of Justice Investigations and civil cases relating to the marketing and sales of generic products. As you may recall, Mayne Pharma and a number of other generic pharmaceutical companies have been sued in civil complaints in the US alleging anticompetitive conduct in the sale of certain generic products. The specific allegations relating to Mayne Pharma focus on the doxycycline hyclate delayed-release market as well as allegations that all defendants were part of an overarching, industry wide conspiracy to allocate markets and fix prices. Mayne Pharma is cooperating with the investigations and strongly defending the allegations made in civil complaints. The Board continues to believe these investigations and civil cases will not have a material adverse effect on the Company's financial position. Since the first investigation began some 2.5 years ago we have



## ASX Announcement

strengthened our compliance culture, enhanced training programs and continued our work to embed compliance into the Company's everyday work practises.

In conclusion, the US pharma sector remains highly 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 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 its key strategic initiatives which include bringing new products to market, optimising our supply chain, exploiting new distribution channels, growing share of marketed products and taking advantage of further business development opportunities.

I do believe we now have a much stronger business following the challenges we faced in 2017. Mayne Pharma will continue to maintain a conservative balance sheet and drive organic growth and seek out value enhancing business development opportunities that can leverage our existing commercial operations and know how. We will also focus on improving profitability and cashflow through an efficient operating model. We have many drivers of near and long-term growth and I am confident we can deliver shareholder value into the future.

Finally, I would like to thank all the employees at Mayne Pharma for their hard work and commitment to deliver on our strategic goals and also thank all our shareholders for your continued support of Mayne Pharma.

With that, I will now hand over to Scott.