



## 2019 ANNUAL GENERAL MEETING

INTERCONTINENTAL MELBOURNE, THE RIALTO  
495 COLLINS ST, MELBOURNE VIC 3000  
AT 10.00 AM ON 22 NOVEMBER, 2019

### 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 2019 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.

As many of you know Ron Best will retire as a Director effective at the end of this Annual General Meeting. Ron joined the Board 13 years ago and helped transition this Company from a small biotech to a specialty pharmaceutical company with a broad portfolio of brands and generic products and contract development and manufacturing services. On behalf of the Board, we would like to thank Ron for his service and significant contribution to Mayne Pharma.

Welcome also to Mr David Petersen, the Company's auditor for FY19 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 outlook; 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.

First of all, I would like to express my disappointment in the financial performance of Mayne Pharma and in the share price which has fallen significantly from \$1.00 this time last year to 55c yesterday. Your Board and management team, who are significant shareholders in Mayne Pharma, are well aware of this and remain focused and highly motivated to turnaround performance and generate shareholder value.

Mayne Pharma's recent performance is in line with many of our US generic peers which have also seen their share prices fall materially and report declining sales and earnings and material impairments of their generic intangible assets. Teva, the largest generic company globally has seen its share price fall 82% over the last 5 years. Mylan, the second largest generic company (which has recently announced a merger with Pfizer's UpJohn business) has seen its share price fall 69% over this same period and Amneal, which are the fourth largest US generic company has seen its share price fall 83% over the last year.

The declining share price performance has been largely due to the disruption we have seen in the US generic industry which has been driven by customer consolidation and the increased speed of approvals through the US Food and Drug Administration (FDA). These challenging market dynamics have driven heightened levels of price deflation and pressure on trading terms which has led to competitors restructuring their operations, withdrawing products and not launching approved products.

Given Mayne Pharma's generic performance and these prevailing market conditions, your Board has reviewed our strategic direction over the last year. Whilst we have opportunities and challenges in the generics sector, our strategic priority is to reposition the business into more sustainable categories and therapeutic areas. Today our focus is clearly aligned to dermatology, women's health, infectious diseases and contract services.

This year we have undertaken a number of actions to better align our business such as streamlining generic drug development, abandoning non-viable projects and focusing portfolio selection and product development on opportunities that align with our core therapeutic channels. We have deepened our external networks of development partners to minimise execution risk, improve time-to-market and identify additional opportunities.

In dermatology, we have expanded our portfolio through the acquisition of LEXETTE® (halobetasol) foam to treat plaque psoriasis and generic EFUDEX® (fluorouracil) cream to treat actinic keratosis and in-licensed a number of other generic dermatology products to leverage our established sales and marketing distribution capabilities in that space.



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We have invested in a new institutional channel field team to market TOLSURA® (SUBA®-itraconazole) antifungal capsules to infectious disease specialists and pulmonologists. The approval and launch of TOLSURA was a key operational highlight for the period and followed many years of development. TOLSURA was developed in Adelaide and is the first New Drug Application (NDA) approved since Mayne Pharma listed on the ASX in 2007.

In women's health, we recently made a significant strategic investment with the licensing of a novel oral contraceptive product E4/DRSP from Mithra Pharmaceuticals (Mithra). We believe this product has the potential to transform our business and our growth trajectory over the coming years. The addition of E4/DRSP contraceptive to the Company's pipeline is highly consistent with our strategy to build our specialty business with durable, high growth novel products in core therapeutic categories leveraging our commercial infrastructure in the US.

Moving to the actual FY19 results.

The Company reported revenue of \$525m down 1% on pcp, reported gross profit of \$290m, up 13% on pcp, reported EBITDA of \$112m down 4% on pcp and underlying EBITDA of \$131m down 20% on pcp. EBITDA was impacted by greater investment in commercial infrastructure to support the recent brand launches of TOLSURA and LEXETTE and additional brand research and development spend which is not generally capitalised.

At the bottom line, the Company reported a net loss after tax which was impacted by intangible asset impairments in the generic area. This impairment is disappointing and resets the balance sheet and is expected to improve reported net profit and earnings per share (eps) in future periods. Net operating cash flow was an inflow of \$107m enabling net debt to reduce in the second half by \$18m to \$280m.

In terms of segment performance, the Generic Product Division sales were \$321m, down 17% on FY18 and gross profit was \$165m down 7% on pcp impacted by competitive pressure on key products. Dofetilide, our largest generic product in FY18 was significantly impacted in FY19 by the anticipated launch of new competitors with sales down by more than 80% to US\$13m driven by pricing pressure and market share loss. Liothyronine, the largest product in FY19, was also impacted by new competition with sales down 42% in the 2HFY19 versus the 1HFY19.

The Specialty Brands Division reported sales of \$92m up 105% on pcp and gross profit of \$80m up 113% on pcp. All products contributed to the growth benefiting from the dermatology sales team expansion in 2018. FABIOR® sales were up 54%, SORILUX® sales were up 26% and the DORYX® family up 153% versus pcp in USD terms. The strong growth in DORYX reflects elimination of the abnormal returns that impacted the prior period and favourable product sales mix. Adjusting for DORYX returns in the prior



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period, the DORYX family and SBD sales were up 42% and 48% respectively on pcp in USD terms.

Metrics Contract Services (Metrics) delivered another strong result with revenue up 14% to \$72m and gross profit up 6% to \$36m. During the period Metrics expanded its commercial manufacturing clients from one to four with one of these clients gaining Japanese (PMDA) approval for a Greenville developed and manufactured product, which is the first international drug approval for the site.

Finally, Mayne Pharma International which includes our Australian operations and export sales grew revenue by 10% to \$41m and gross profit increased 25% to \$10m. This segment benefited from growing sales of SUBA-itraconazole and KAPANOL® globally, new third-party contract development revenues and milestone payments from the out-licensing of key specialty products globally.

Now I would like to make some comments on the changing profile of our business. As I mentioned earlier, we are actively repositioning the business towards more protectable revenue streams by focusing on women's health, dermatology and infectious disease.

In dermatology, we have been actively expanding our portfolio with additional generic and brand products and continue to have discussions with a number of third parties around further product collaborations. Longer term we expect to benefit from the commercialisation of our two important rare skin disease clinical programs under development:

- SUBA-itraconazole as a potential treatment for Basal Cell Carcinoma Nevus Syndrome (BCCNS) which is going into phase 3; and
- trifarotene for the treatment of congenital ichthyosis, which is currently in phase 2.

In infectious disease, TOLSURA is expected to be a key growth product over the next two years.

In women's health we have an extensive portfolio of branded generic contraceptives and a pipeline that includes generic NUVARING®, the largest contraceptive product sold in the US and E4/DRSP, the novel contraceptive product we recently licensed from Mithra in the field of oral contraception in the US. E4/DRSP is a combined hormonal contraceptive composed of Estetrol (E4), a new and novel estrogen and drospirenone (DRSP), a progestin. Estetrol is the first native estrogen with selective actions in tissues and has potential application in various fields including contraception and menopause. E4/DRSP is expected to be commercialised in the first half of calendar 2021, subject to US FDA approval. Women's health is expected to become Mayne Pharma's largest therapeutic category following the launch of these two key pipeline products.

The E4/DRSP transaction which we completed last week, following US Federal Trade Commission (FTC) clearance, strengthens our collaboration with Mithra who is also our



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partner for generic NUVARING. We are extremely pleased that Mithra selected Mayne Pharma to distribute its key pipeline product in the US and have taken a strategic shareholding in our Company. Mithra currently holds 4.95% of our issued capital and will hold up to 9.6% upon regulatory approval of E4/DRSP. Mithra chose Mayne Pharma to commercialise its leading product candidate in the US which supports the depth of our relationship and the confidence Mithra has in the ability of Mayne Pharma's commercial infrastructure. Mithra has a number of other women's health products in its development pipeline and we hope to add further collaboration opportunities in the future.

In FY19, dermatology, women's health and infectious disease products represented 34% of group revenue. Following the successful commercialisation of E4/DRSP, generic NUVARING and TOLSURA we expect these three categories to grow over the next 4-5 years to represent more than half of our portfolio with retail generics falling to less than a quarter. This transformation of our sales mix should lead to more sustainable earnings and position Mayne Pharma as a key player in the women's health space.

Finally, I would like to thank all the employees and our leadership team, many of whom are here today for their hard work and commitment. I would also like to thank all our shareholders for your patience, loyalty and support during these difficult times.

With that, I will now hand over to Scott.