



## ANNUAL GENERAL MEETING

MINTER ELLISON  
LEVEL 23, 525 COLLINS ST, MELBOURNE VIC 3000  
AT 11.00 AM ON 29 NOVEMBER, 2016

### CEO'S ADDRESS

Thank you Roger. Good morning Ladies and Gentlemen.

It is a pleasure to be speaking to you today at the Mayne Pharma AGM.

In summary, our business has had a strong start to the financial year with group revenue to the end of October up 104% to \$172m versus the prior corresponding period. There was strong growth across Generic Products, Contract Services and Mayne Pharma International. The Specialty Brands Division performed well despite temporary headwinds from the loss of exclusivity on Doryx<sup>®</sup> 50mg and 200mg in May and is well placed for future growth with the recent launch of Doryx MPC, and the impending launches of Fabior<sup>®</sup> and Sorilux<sup>®</sup>.

The solid operating performance of the US business was impacted by the strengthening US dollar versus the prior year but the group benefited from a \$26m cash settlement of US patent litigation which is recorded separately as additional income and is not included in the revenue figure above.

I will now take you through the performance of the group in more detail.

### Generic Products Division (GPD)

Moving to the US Generic Products Division or GPD. Year to date sales are up 352% on the prior corresponding period to US\$97m and up 330% in AUD terms driven by the Teva product portfolio acquisition and strong growth in our existing business. The base business has grown 96% to US\$42m with dofetilide, BAC products and methamphetamine being the key contributors. As expected, dofetilide became the largest selling product in the GPD portfolio, accounting for 16% of sales across this period and is now the market leader in terms of volume share following outstanding launch execution.

Sales from the Teva acquisition over the first 59 trading days since closing on August 4 to the end of October were US\$55m. We have been pleased with the overall performance of the recently acquired basket of products and the operational execution of this complex transaction. All on-market products were available for sale at completion and we have not suffered any stock outs. Although the portfolio has

showed volatility in terms of monthly volumes as the business is transitioning, the year to date performance is in line with our expectations from a sales and margin perspective with the oral contraceptive portfolio in particular performing strongly. Pleasingly the gross margin performance of the acquired portfolio has tracked above 50%, in line with our original guidance.

We expect monthly revenue and earnings from the Teva portfolio to grow over the remainder of the financial year as we continue our customer on boarding process and pursue new account wins. Additionally, the recent launch of budesonide in October was achieved on time and this is the largest pipeline product acquired from Teva with IMS annual market sales of US\$320m<sup>1</sup>. In summary, we are confident we will achieve the revenue and earnings guidance provided at the time of the acquisition when compared on an annualised basis.

In November, we began to see the first revenue synergies materialise from the transaction with the listing of several existing products on the US government Federal Supply Schedule, including dofetilide and oxycodone/APAP. We have already secured new contracts in November with an annualised earnings contribution exceeding US\$2m and will continue to expand this new channel across fiscal 2017.

Cost synergies will start to be realised in fiscal 2018 following the transfer of products out of Teva's facilities into either our own facilities in Greenville or Salisbury, or into our network of contract manufacturing organisations (CMOs). Product margins are expected to improve from this supply chain optimisation as we access lower manufacturing costs and gain overhead recovery throughput benefits across our internal network.

These product transfers and the facility expansions we previously announced are tracking to plan. In Australia, the transfer of carbidopa/levodopa tablets is well underway with exhibit batches now manufactured. This product is expected to become the largest volume product at the Salisbury site and provide more than US\$2m of annual overhead recovery benefits. In addition, the business has identified more than US\$10m of annual cost synergy benefits from the transfer of products out of Teva's facilities.

Other recent highlights in this division include the launch of morphine sulfate ER tablets and temozolomide capsules. These products participate in competitive markets with IMS annual sales of US\$270m and US\$150m respectively<sup>1</sup>.

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<sup>1</sup> IMS Health MAT September 2016

## Metrics Contract Services (MCS)

Metrics Contract Services, or MCS, is our fee-for-service business offering clients an array of services from analytical chemistry to formulation development. This business continues to perform strongly with revenue up more than 23% on the prior corresponding period in USD terms and 17% in AUD terms.

Growth in this business is being driven by continuing to attract new business, together with targeting higher value, later stage development work. Further, our investment in an analytical lab efficiency program continues to enhance our service levels through faster turnaround times for clients while also delivering improving operating margins. Revenue per employee has increased 20% since implementing this efficiency program in the second half of FY16. The outlook for MCS remains positive with a strong book of committed business underpinned by solid market growth dynamics.

## Specialty Brands Division (SBD)

Specialty Brands Division, or SBD, is responsible for the sales, marketing and distribution of branded pharmaceuticals. Today the sales team are promoting the Doryx franchise and from early next year will additionally commence promotion of our two dermatology foam products, Fabior and Sorilux which we acquired from GlaxoSmithKline (GSK) in August.

SBD year to date revenue is down 44% on the prior period to US\$11m, impacted by the loss of exclusivity on 50mg and 200mg Doryx in May. As expected, July and August sales for branded Doryx were soft, in part due to destocking in the trade channel. Net revenue has since strengthened in September and October and consequently, average net sales are up 50% as compared to the first two months of the financial year.

Pleasingly, the in-market performance of the 50mg and 200mg Doryx franchise has tracked very well since May, holding onto around 80% of total prescriptions (TRx's) written. Doryx MPC which was launched in August is a new formulation that incorporates our multi-particulate drug delivery technology. Doryx MPC has two orange book listed patents that expire in 2034 and we continue to pursue further patent protection.

The key priorities for SBD have been to improve sales force effectiveness, grow prescription volume and prescription profitability. To that end, Doryx MPC is now tracking at 1,000 scripts per week and growing the overall Doryx franchise<sup>2</sup>. Since the launch of Doryx MPC, Mayne Pharma's total doxycycline franchise prescriptions are up 20% to 4,300 scripts per week<sup>2</sup>. Just recently, one of the nation's largest payers added Doryx MPC as a preferred brand to their formulary mid-year, immediately increasing

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<sup>2</sup> IMS Health, US weekly prescription volume, data up to week ending 11 November 2016

access for patients. We remain focused on broadening coverage under this strategy with third party payers and we expect this to increase access for acne patients and profitability of Doryx MPC over the coming year.

The launch of Fabior and Sorilux in early 2017 is expected to contribute to a much stronger second half for SBD. These two products are clinically differentiated, have patent protection and are highly complementary to the Doryx franchise. Fabior – a topical acne support therapy - participates in the single active retinoid market in which 5 million prescriptions are written per annum. This market is significantly larger than the Doryx market as topical products are used more frequently by acne patients across the disease spectrum from mild and moderate to severe acne cases. Sorilux is a topical foam product used to treat mild to moderate plaque psoriasis.

As we prepare for launch our expectations for these products has grown. The foam delivery platform has a well established reputation with dermatologists due to ease of application, especially in hair bearing areas and under clothing. Both products have strong clinical data supporting efficacy and in the case of Fabior it has shown to be well tolerated across patient types.

The launch of Doryx MPC and the GSK product acquisitions has provided the basis for internalising the Doryx sales team from inVentiv, a contract sales organisation. This will be completed by the end of the calendar year and benefits are expected to include cost synergies, improved ability to attract and retain talent, improved performance management and ultimately improved sales force effectiveness.

## Mayne Pharma International (MPI)

The final business segment is Mayne Pharma International or MPI. MPI's sales revenue reflects domestic sales and revenue from the export of our products to international markets other than the US. This segment grew sales 14% over the prior period driven by growth in export sales. Although the Australian business was flat on the prior period, Lozanoc<sup>®</sup>, oxycodone and injectables grew offset by softer Kapanol<sup>®</sup> sales.

## Pipeline

With enlarged earnings and operating cashflows following the recent acquisitions we are stepping up our investment in R&D. This year we are investing more than A\$40m in research and development of which over \$15m will be spent on pivotal biostudies to support the registration of generic products and \$10m on branded projects.

The R&D program has historically focused on developing potent compounds, controlled substances and utilising our drug delivery technologies. Going forward, we will expand our access to complementary drug delivery technology through collaborative development arrangements, strategic partnerships and targeted acquisitions. The Teva acquisition has introduced multiple new suppliers and

developers to our network and we are currently exploring a number of new pipeline opportunities with them that leverage alternative drug delivery platforms. Further, the recent GSK foam product acquisition has provided Mayne Pharma with access to a new technology platform and we have already identified a number of new branded product opportunities. The new foam platform includes a state of the art foam filling line which we acquired from GSK for US\$1.4m and plan to install at an experienced foam contract manufacturer in the US. Foam is an innovative delivery system with technological barriers due to complex development, clinical challenges and the requirement for highly specialised manufacturing facilities.

We believe the key to future sustainable growth for the company will come from leveraging and extending our drug delivery technologies coupled with rigorous and robust portfolio selection processes. The GSK foam assets acquisition is right on strategy in this regard.

Another priority for our R&D team is to increase investment in paragraph IV development programs. Although higher risk, we believe we have the capability and track record to identify and successfully prosecute these opportunities and have hired in new talent to drive this strategy. The recent launch of dofetilide in June, our first first-to-file paragraph IV program, has delivered returns on invested capital of more than 300% in its first 5 months of sales.

Today, we have more than 40 US pipeline products targeting markets with annual sales of more than US\$6 billion of which 18 products are pending approval at the FDA targeting addressable markets with sales greater than US\$1.3 billion<sup>3</sup>. Of the 18 pending products, 5 products have no generic competitors and 14 products have 3 or less generic competitors.

## HedgePath Pharmaceuticals

I also wanted to briefly mention our strategic investment in HedgePath Pharmaceuticals, a US OTCQB Market listed public company. We currently own approximately 55% of the common stock in HedgePath which is seeking to repurpose our SUBA<sup>®</sup>-Itraconazole product in various cancers. Recently, HedgePath announced positive interim data from a Phase IIb clinical trial in patients with a genetic form of skin cancer called Basal Cell Carcinoma Nevus Syndrome (BCCNS) – more commonly known as Gorlins Syndrome - supporting the hypothesis that SUBA-Itraconazole can inhibit tumour growth.

Eighteen subjects with Gorlins have completed the scheduled 16 weeks of dosing. Analysis of the data shows 141 lesions (61% of those studied) have responded to therapy with either a partial or complete response and 229 target lesions (99% of

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<sup>3</sup> IMS Health MAT September 2016



## ASX Announcement

those studied) have not progressed (meaning they have not grown more than 20% in size). Independent analysis of the target lesions reported that 71 tumours (or 31% of the target lesions studied) demonstrated a complete response and an additional 70 tumours (or 30% of the target lesions studied) demonstrated a 30% or greater reduction.

In June, the FDA granted Orphan Drug Designation and HedgePath will be seeking 'Breakthrough Therapy Designation' which would permit the filing of a rolling new drug application and accelerated review by the FDA for the use of SUBA-Itraconazole for the treatment of non-metastatic basal cell carcinoma in patients with Gorlins Syndrome.

We are excited about the potential of SUBA-Itraconazole in Gorlins and potentially other cancers. There are approximately 10,000 patients with Gorlins in the US. There are no drug products approved to treat this disease and the standard of care is surgical excision which can lead to significant scarring and disfigurement often in the facial area.

On the business development and M&A front we continue to actively pursue opportunities to expand our product portfolio and pipeline through in-licensing or acquisition.

In summary, we have multiple opportunities for growth across our four business segments. Recent product acquisitions, new product launches and the extraction of revenue and cost synergies will drive this growth.

To conclude, I would like to thank the Mayne Pharma Leadership Team, the board and all our employees for their hard work and passion. I am confident that we have the right businesses, with the right strategies and the right talent to drive sustainable value for you, the Mayne Pharma shareholders, into the future.

I will now hand back to Roger to complete the formal part of the meeting.