



## ANNUAL GENERAL MEETING

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

### CEO'S ADDRESS

Thank you Roger. Good morning Ladies and Gentlemen.

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

As Roger mentioned the US pharma market is extremely dynamic. There's a lot going on – whether it be commentary about potential regulatory and legislative changes focused on bringing down drug prices; vertical mergers of drug store chains, pharmacy benefit managers and insurers; through to, major pharmaceutical manufacturers restructuring their operations, closing plants, and divesting or withdrawing unprofitable products. During this dynamic period the generic market in which Mayne Pharma participates has shown signs of relative stability compared to this time last year as it appears our industry is generally focused on profitability rather than volume and topline sales growth.

Notwithstanding these dynamics, the US remains the world's largest pharmaceutical market by far, representing 44% of global sales<sup>1</sup>. Interestingly, approximately two-thirds of this value is captured by wholesalers, retail drug chains, pharmacy benefit managers and insurers, downstream from manufacturers like Mayne Pharma.

Against this backdrop, 3 of the top 10 Fortune 500 companies are making investments into the healthcare space. Berkshire Hathaway, JPMorgan and Amazon have partnered to create a venture aimed at reducing employee healthcare costs; Apple is setting up employee medical clinics to manage its own healthcare costs and Amazon has recently acquired PillPack, an online full service pharmacy, which is seen as a deal that could be the start of Amazon becoming a significant disruptor in drug distribution.

Given these industry dynamics, a key focus of Mayne Pharma today is to get closer to the patient, participate in other parts of the value chain and find more efficient and cost effective ways to get our products to patients. Together with building a sustainable pipeline of valuable products, this is central to our long term competitive position and success.

---

<sup>1</sup> IQVIA, NSP Sales, Jun 2018



## ASX Announcement

Now to the 4-month year to date trading update:

In revenue terms, our business has had a good start to the financial year with group revenue to the end of October up 21% to \$183m versus the prior corresponding period (pcp). All four segments contributed to this growth and pleasingly, three segments delivered double digit revenue growth in AUD terms.

In gross profit terms, the business has delivered strong results, generating a gross profit of \$108m, up 75% on pcp with a corresponding gross profit margin of 59%. This strong margin improvement reflects a greater contribution from Specialty Brands which has a high margin profile, cost savings from bringing manufacturing in-house from third parties, favourable product sales mix in generics and normalised levels of stock obsolescence and Doryx® returns.

Foreign currency has been a tailwind over the period with the average USD FX rate strengthening six cents to 0.726 versus pcp. With 90% of our assets and revenue in USD, a strengthening US dollar is positive to earnings and our net asset value. In terms of earnings, the impact is greater at the EBITDA level and modest at the reported NPAT level due to the fact that 80% of our expenses (operating, depreciation, amortisation and interest) are also in USD.

One final point I would like to highlight on the group result is we expect to see an increase of ~15% in depreciation and amortisation this year based on current exchange rates following completion of the capex expansion programs in Greenville and Salisbury and additional amortisation for the two dermatology product acquisitions (generic Efudex® and halobetasol foam) we completed this year.

In terms of cash flow, we have generated positive operating cashflow in the first four months of this year which is down 10% on pcp largely driven by an extension of trading terms this half from one of the major wholesalers and working capital build for the generic Efudex acquisition. This one-off trading terms impact is expected to return normalised levels in the second half.

I will now take you through the performance of each of the segments.

### Generic Products Division (GPD)

GPD year to date sales were \$120m up 8% on the prior corresponding period. In USD terms, sales were US\$87m, in line with last year and unit volumes also held steady. Gross margin continues to strengthen this year and was above the gross margin we experienced in the 2HFY18.

Whilst dofetilide has been our largest and most successful product launch in our short history, it has been impacted, as anticipated, by the approval of 4 new competitors this year. Dofetilide sales were down 65% on pcp to US\$7m driven by pricing pressure,

market share loss and shelf stock adjustments. We are working to offset this headwind through recent product launches such as generic Efudex which is now in our top 10 generic products and liothyronine, which has captured more than 35% share of total prescriptions since its launch in January this year<sup>2</sup>. Other products which have contributed favourably to performance this year include amiodarone which has benefited from transfer of manufacturing in-house to Greenville, the butalbital family has had a new product launch this half - butalbital / APAP capsules - and the oral contraceptive portfolio has experienced significantly reduced stock obsolescence. The level of stock obsolescence continues to remain below our targeted rate of 3% of sales.

In terms of our pipeline we continue to invest in the development of first-to-market opportunities, and hard to develop and manufacture products utilising our drug delivery technologies and potent drug handling capabilities. In addition, we are investing in a number of topical product clinical end point programs to support our growing dermatology franchise.

Today, we have more than 25 pipeline products targeting markets with annual sales of more than US\$5b<sup>3</sup>, of which 15 products are pending approval at the FDA. Over the coming year, we expect to see a number of pipeline launches, including several potential first-to-market launches. In the first four months of this fiscal year, the Company added two further topical products into development targeting markets with sales of US\$400m<sup>3</sup>.

The most significant product in our filed pipeline is generic NuvaRing®, the largest contraceptive product sold in the US by sales. This is a complex and difficult to develop and manufacture product targeting the US\$910m<sup>3</sup> NuvaRing market. The Company is responding to a number of review questions from the FDA and hopes to bring generic NuvaRing to market in a timely matter. Pleasingly, Mithra, our partner for this product, was the first Company to receive a generic NuvaRing approval in Europe, which occurred in July this year.

### Specialty Brands Division (SBD)

Specialty Brands Division, or SBD, is responsible for the sales, marketing and distribution of specialty pharmaceuticals in the US. Today the sales team is promoting three dermatology products; Fabior® (tazarotene) foam and Doryx MPC (doxycycline) tablets used to treat acne and Sorilux® (calcipotriene) foam which is used to treat psoriasis.

SBD year to date revenue was \$26m, up 267% on pcp. In USD terms, revenue was US\$19m, up 235% on pcp. The strong growth year on year reflects good momentum with Fabior and Sorilux with revenue up 170% and 108% respectively on pcp and the elimination of abnormal Doryx returns which impacted the prior period.

---

<sup>2</sup> IQVIA weekly TRx, 16 Nov 2018

<sup>3</sup> IQVIA NSP MAT Sep 2018

In terms of underlying demand as measured by dispensed prescription data, the three branded products Fabior, Sorilux and Doryx MPC have demonstrated strong growth up 34% year on year with Sorilux up 136%, Fabior up 54% and Doryx MPC remaining steady<sup>4</sup>. The strong growth of the foam brands has been driven by the expansion of the dermatology sales team this time last year.

In early 2019, the Company plans to launch Lexette™ (halobetasol) foam which is a corticosteroid also used to treat psoriasis. Lexette will be marketed by our existing SBD sales team. We will now be able to offer patients a potent steroid along with steroid-free Sorilux giving them more treatment options with the benefits of the foam formulation.

Lexette forms part of the US\$600m<sup>5</sup> topical corticosteroid market which is the cornerstone of treatment for the majority of psoriasis patients. Dermatologists often prescribe more than one product to treat psoriasis and many use a corticosteroid such as Lexette together with a Vitamin D analogue such as Sorilux.

The company also expects to launch Tolsura™, our US brand name for SUBA®-itraconazole capsules for the treatment of certain fungal infections in early 2019. Tolsura is in late stage review by the FDA and has a PDUFA goal date of 16 Dec 2018.

In anticipation of approval, we are in the process of recruiting a new hospital sales and account management team of approximately 15 staff to promote Tolsura.

Tolsura is expected to be used to treat a number of systemic fungal infections which most commonly occur in vulnerable or immunocompromised patients, for example, those with a history of cancer, solid organ or bone marrow transplants or HIV/AIDS and are often associated with high mortality rates or long-term health issues.

The US anti-fungal triazole market has a current value of US\$600m<sup>5</sup> and based on a clear unmet clinical need in serious systemic infections, the addressable market for Tolsura will be approximately US\$200m<sup>6</sup> per annum.

With the launch of Lexette and Tolsura this financial year, the Company will be investing in additional expenses covering sales and marketing and clinical spend to support the commercialisation of these products. We expect to invest approximately US\$4m in operating expenses for each of these products across FY19 with both products expected to be earnings accretive in the first full year following launch.

We are very excited about the potential of both Lexette and Tolsura and expect both products to be key drivers of future growth.

---

<sup>4</sup> IQVIA monthly TRx, YTD Nov 2018 versus YTD Nov 2017

<sup>5</sup> IQVIA NSP MAT Sep 2018

<sup>6</sup> Management estimate

We also remain confident about the potential for repurposing SUBA-Itraconazole in certain cancers and are pleased with the results that have been achieved in the Phase IIb clinical trial conducted by our subsidiary, HedgePath Pharmaceuticals in patients with a genetic form of skin cancer called Basal Cell Carcinoma Nevus Syndrome or BCCNS.

Some of you may be aware of some press around the potential exercise by the Company of an option to take back BCCNS in the US. We are working hard to achieve a solution that is in the interests of all stakeholders and will update the market once we have a clear pathway forward.

In addition to these brand programs, Mayne Pharma is also investing in earlier stage projects and expanding the clinical use of the current on market portfolio. The Company has three early stage dermatology foam products in development and is also developing the novel topical retinoid trifarotene targeting specific rare dermatological diseases.

This additional brand R&D spend this year has resulted in the level of R&D capitalisation declining significantly as a result and was approximately 50% in the first four months of this fiscal year versus 73% in the pcip.

### **Metrics Contract Services (MCS)**

Metrics Contract Services, (MCS or Metrics), is our fee-for-service business offering clients an array of services from analytical chemistry, formulation development to commercial manufacturing. This business achieved year to date revenue of \$22m up 13% on pcip and in USD terms, MCS revenue was US\$16m up 4% on pcip.

This business has enjoyed strong growth for many years outperforming market growth rates through strong retention of its customer base, a track record of scientific and technical excellence, exceptional customer service and the strategic investments made in Greenville over the last three years in new technology and manufacturing capacity.

Whilst the first four months have seen softer growth than prior years in USD terms, all key performance measures are trending favourably for strong growth over the remainder of the financial year. Our committed business outlook which is the next six months of signed work orders is up 50% in dollar terms since this time last year, and the value of quote dollars won is up 22% on pcip.

Further, the pipeline of commercial contract manufacturing revenue continues to build. Metrics expects to be an approved supplier in at least 10 marketing applications over the next few years. This includes on-market commercial products that Metrics is already in the process of qualifying at the Greenville site, including EU and Japanese qualifications expected in 2019. This robust pipeline is expected to deliver a growing base of recurring manufacturing revenues over time.

## Mayne Pharma International (MPI)

Mayne Pharma International reflects Australian domestic sales and revenue from the export of our products to international markets other than the US. This segment grew sales 13% to \$14m compared to the prior corresponding period. The stronger performance was driven by new product launches and growing global sales of itraconazole and morphine.

So to conclude, our strategic priorities have not changed. We are focused on creating value for our shareholders through exploiting new distribution channels, growing share of marketed products, bringing new products to market, optimising our supply chain and further business development activity. Mayne Pharma's strength lies in its integrated operations and commercial platforms that are based in the world's largest pharmaceutical market. I believe our diversified business is a competitive advantage over similar sized peers and de-risks our business model which we aim to further enhance over the medium to long term by rebalancing our portfolio with a greater contribution from Specialty Brands, Metrics Contract Services and Mayne Pharma International.

Finally, I would like to thank the Mayne Pharma Leadership Team, the Board and all our employees for their hard work, commitment and passion.

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