



# ASX Announcement

## ANNUAL GENERAL MEETING

RACV CLUB  
LEVEL 2, 501 BOURKE ST, MELBOURNE VIC 3000  
AT 11.00 AM ON 28 NOVEMBER, 2017

### CEO'S ADDRESS

Thank you Roger. Good morning Ladies and Gentlemen.

Today I will provide you with an update on our results, how our pipeline is progressing and our strategy for future growth.

Before I comment on our results, I would like to make some opening remarks about the US generic marketplace. As most of you know, the sector is facing a tough deflationary period driven by recent aggressive contracting behaviour from the major wholesaler/retailer buying alliances which today account for around 85% of retail generic drug purchasing together with a speed up of approvals through the US FDA. These changing market dynamics have impacted the whole generic industry leading to many of our US peers reporting heightened levels of price deflation, together with softening sales, margins and earnings.

Our view is this buy-side behaviour is not sustainable long term. The generic industry is essential to the US healthcare system as it saves patients and payers billions of dollars each year. The demand for generic medicines will continue to increase and today generics are responsible for 90% of all prescriptions dispensed in the US.

Generic manufacturers are an essential part of the supply chain deploying significant risk capital through investment in R&D and infrastructure to develop and manufacture products to ever-increasing quality and regulatory standards. Manufacturers will exit product markets and channels if satisfactory economic returns cannot be realised or they will find more efficient ways to get their products into patients' hands. In simple terms, the large buyers of generic medicines need a healthy and dedicated Mayne Pharma and others like us to continue re-investing in pipeline and capacity as the overall market continues to grow. It should be noted that this recent downward pressure on pricing has not resulted in consumers paying less for medicines which suggests incremental profits from this contracting behaviour are being trapped in the supply chain between the manufacturer and the patient.

Mayne Pharma is in a strong position to weather these challenging conditions, with a solid balance sheet, a diverse operating model that also includes specialty brands and contract services, and an experienced team of people to lead and execute on our strategies including stabilising our generic business and bringing it back to growth. We have also continued to invest in our facilities and diversify our pipeline via investing in



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clinically differentiated branded product development and complex generic programs. We expect these will be tremendous assets in the future that will drive long term sustainable growth.

Moving to the results.

Group revenue to the end of October was down 12% to \$151m versus the prior corresponding period (pcp) impacted by buy-side contracting behaviour just mentioned. In addition, year to date results have also been impacted by a number of abnormal one-off items which include extraordinary stock obsolescence charges and sell through of short dated stock below cost following the significant investment in inventory to support the Teva portfolio acquisition. Further, we have seen significant abnormal Doryx® returns emanating from the generic event on legacy Doryx 50mg and 200mg tablets in May 2016. Both of these items are expected to return to normal levels in the second half. Adjusting for these one-off items, group revenue would have been down 8% on pcp and the gross profit margin would have been 50% to the end of October instead of 41%.

Pleasingly, there have been no further increases in working capital over the period and we are starting to see this unwind with operating cash flow more closely following accounting profit.

While this performance will result in a soft first half, we are working on a range of initiatives which we expect will vastly improve future performance, and which are already yielding improved trading results in October and the present month. For example, generic products net sales and gross profit were up 25% and 50% in October versus the monthly average in the 1Q18 and Specialty Brands adjusted net sales (excluding Doryx returns) were up 35% in October versus the monthly average in the 1Q18.

These initiatives include expansion of the dermatology sales team driving greater prescription demand across our 3 brands, cost savings from further restructure of our supply chain network and operating expense base, improvement in co-pay management for our branded products, new opportunities to gain market share in existing and new channels for our generics business, and of course new product launches. Together with normalised levels of product returns and stock obsolescence, these initiatives are expected to drive a very strong recovery in financial performance in the second half and beyond.

To further assist the recovery, we are making a number of changes to our business to restructure the balance sheet and improve our cost base. These include:

- Firstly, \$13m restructuring charge covering abnormal stock obsolescence and Doryx returns, and renegotiation of supply chain contracts and other expense management initiatives. These changes are anticipated to drive benefits of \$5m in 2H18 and \$7m annualised; and

- Secondly cancelling up to 16.5m employee shares on issue at a one-off, non-cash cost of up to \$7.4m. These shares which are not effectively incentivising our employees would have an accounting expense (if not cancelled) of \$3.4m in FY18 and have a current value of almost zero. This initiative will allow alternate opportunities to be considered to more effectively incentivise employees going forward.

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

## Generic Products Division (GPD)

In terms of the segment performance, GPD year to date sales were down 10% on the prior corresponding period to US\$88m with price deflation pressures driving the decline. Gross margin has also been impacted by US\$7m of abnormal stock obsolescence and sell through of short dated stock below cost to mitigate the full obsolescence risk just outlined. Adjusting for these one-off items, the generic gross profit margin would have been 46% instead of 38%.

In terms of key product performance, dofetilide remains our largest selling product and retained 60% market share of total prescriptions<sup>1</sup>. Doxycycline hyclate IR tablets (generic Acticlate®) became one of our top 5 products in the quarter capturing 30% market share of weekly prescriptions<sup>1</sup>. Offsetting these were declines in the oral contraceptive products acquired from Teva and the BAC franchise.

To mitigate the current pricing pressures, we are focused on executing a number of initiatives including expanding and diversifying channels to market, extracting cost savings from optimising our supply network, growing share of marketed products through aggressively pursuing new opportunities and maximising the launch of new products.

In terms of expanding channels – we are focused on growing our business in government, specialty pharmacy and institutional or hospital channels. New systems and management in this area have helped us to grow these channels significantly over the last year with non-retail channels now representing 15% of GPD sales this year versus 8% in the pcp. In the last month, we have begun the process of expanding our product offering on the Federal Supply Schedule (FSS) which enables the Company to participate in the US\$11b government market through the Department of Veteran Affairs, Department of Defense and other federal agencies.

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 is progressing well and we expect to achieve at least US\$12m of cost savings on an annual basis from

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<sup>1</sup> IQVIA IMS Health weekly TRx data as at 17 November 2017



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these transfers. Timing of these cost savings remains on track such that the majority will be achieved in FY19.

In the last three months, we have reorganised our commercial team, strengthening selling processes and financial reporting to concentrate on our key products, channel and customer opportunities. We are beginning to see the benefits of these changes with several new major customer wins in November.

Trade unit volumes, net sales and gross margin were up 12%, 25% and 50% respectively in October versus the monthly average in the 1Q18 and based on the latest daily sales report, we expect November to be in line with October's improved result.

We have many emerging opportunities to execute on with near term impact, and for these reasons, together with the non-recurring nature of the stock obsolescence levels we have endured this half, I am very confident that we can return GPD to strong growth in the second half of this financial year.

The key to success in the retail generic market is having a portfolio of differentiated products which typically have less than 3 competitors, a competitive product cost base together with a reliable and quality supply chain. Approximately 60% of our on-market portfolio fits this competitive market criteria. In the last 18 months, Mayne Pharma has demonstrated outstanding returns that can be achieved from generic R&D investment. Dofetilide capsules and doxycycline hyclate IR tablets have together delivered gross margin of US\$60m since launch and returns of over 1000% on their development and related litigation costs.

### *Generic pipeline*

In terms of the generic pipeline, Mayne Pharma continues to invest in the development of new products focusing on higher value and niche product opportunities, first-to-market generics and hard to develop and manufacture products utilising our drug delivery technologies and potent handling capabilities. In the last year, we have significantly expanded our capabilities through developing a number of strategic alliances with best in class drug developers and manufacturers. We partnered with Douglas Pharmaceuticals for semi-solid and soft gel products requiring specialised high containment manufacturing, Corium for transdermal patches and with Mithra for women's health hormonal devices.

Today, we have around 35 generic pipeline products targeting markets with annual sales of more than US\$5b of which 17 products are pending approval at the FDA. In the first four months of this fiscal year, the Company filed 3 products with the FDA targeting markets with sales of US\$200m<sup>2</sup> and added 2 further products into development targeting markets with sales of US\$100m<sup>2</sup>.

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<sup>2</sup> IQVIA IMS Health NSP MAT Sep 2017

In FY18, the Company expects to receive approval for 6 products targeting markets with sales of US\$500m<sup>3</sup>. Two products clozapine tablets (generic Clozaril®, an anti-psychotic) and doxycycline capsules (generic Monodox®, an anti-infective), have already been approved and clozapine tablets launched earlier this month and doxycycline capsules will launch in the new year. Other approvals expected include a potential first to market opportunity.

In FY19, the Company is expecting a much stronger generic pipeline to drive growth with approximately 8 potential launches targeting markets with sales of US\$2b<sup>3</sup>. The most significant of these is Myring (generic Nuvaring®) the largest contraceptive product sold in the US. Myring is a complex and difficult to develop and manufacture product targeting the US\$800m<sup>3</sup> Nuvaring market and complements our existing women's health franchise of 20 oral contraceptive products. This month Mithra announced the successful completion of its bioequivalence study which used product made from its new commercial manufacturing facility in Belgium.

Pleasingly, the FDA has improved its review times with expedited review now granted for a generic application until there are three approved generics for a given drug product. Expedited review reduces the review time from 10 months to 8 months. Currently, Mayne Pharma has 20 products (of which 7 are filed with the FDA) in its pipeline that could apply for expedited review targeting markets with sales of US\$3b<sup>3</sup>.

## Metrics Contract Services (MCS)

Metrics Contract Services, or MCS, 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 US\$15m up 7% on the prior corresponding period. All key performance measures are trending favourably for strong growth over the remainder of the financial year with committed business<sup>4</sup> up 15% since this time last year and the value of quote dollars won up 50% on pcp from US\$11.9m YTD17 to US\$18.1m YTD18.

This business has enjoyed growth for many years and has outperformed market growth rates through strong retention of its customer base, a track record of scientific and technical excellence and exceptional customer service. Metrics has a diverse blue-chip client base focused on novel drug development and commercialisation. Importantly the largest MCS client represents just 9% of sales.

With the new Greenville facility due to be operational early calendar 2018, we expect to transition Metrics Contract Services from a project based revenue stream to include a mix of ongoing recurring revenue streams related to commercial manufacturing

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<sup>3</sup> IQVIA IMS Health NSP MAT Sep 2017

<sup>4</sup> Committed business pipeline is the next 6 months of signed purchase orders / statements of work

opportunities. Metrics has supported registration batch manufacture for 5 programs already, and another 8 programs are scheduled in 2018. This work along with further late-stage development and technology transfer programs are growing the pipeline of commercial manufacturing opportunities in our new facility which is proving to be of great interest to our existing customer base as well as potential new customers. Currently the business has 19 quotes issued with peak aggregate annual unit demand of 130m units.

## 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 three dermatology products; Fabior® and Doryx both used to treat acne and Sorilux® which is used to treat mild to moderate plaque psoriasis. All three products are patent protected, differentiated brands and compete in attractive markets with limited competition from other brands.

SBD year to date revenue was US\$6m, negatively impacted by US\$6m of Doryx returns which relate to the generic event and loss of exclusivity on legacy Doryx products in May 2016. Excluding Doryx returns, which are one-off in nature, SBD revenue would have been up 8% on pcp.

In addition, we have experienced lower trade volumes in the 1Q18 which is a timing issue and is not a reflection of reduced underlying demand measured by script performance. Softer sales across our dermatology portfolio reflects seasonality of these products through the summer months, a price rise on Fabior which resulted in strong sales in June, and additional loyalty card costs following a one-off promotional offer on Fabior in August. SBD year to date results are not at all reflective of the underlying potential of this segment.

Trade unit volumes and adjusted net sales (excluding Doryx returns) were up 30% and 35% respectively in October versus the monthly average in the 1Q18 and based on the latest daily sales report, we expect to see further growth in sales in November over October.

The underlying demand performance of these products, measured by dispensed prescriptions, was up 35% in October versus pcp and up 13% on the prior month with the three franchises tracking around 5,500 prescriptions (TRx) per week. Fabior is tracking at 1,400 TRx per week, Sorilux 450 TRx / week and the Doryx franchise at 3,700 TRx per week. Both Fabior and Sorilux have exceeded the previous peak prescription volume achieved by the former brand owner.

These results are yet to see the impact of the second sales team which is currently under recruitment and on track to be on board and trained by mid-December. As of today, we have 42 of the additional 60-person sales team on board and commencing field

activities. We expect this second sales team will accelerate market share and growth of these three dermatology brands as well as support any further brands that are added to the dermatology portfolio.

Fabior and Doryx are highly complementary as both products are used to treat acne across the disease spectrum and many acne patients will be treated with both an oral antibiotic like Doryx and a topical retinoid like Fabior. Acne is the most prevalent skin disorder in the US, with an estimated prevalence of more than 50m people. The total tetracycline market for Doryx is worth US\$750m or 3m prescriptions per annum and the Doryx franchise currently has an 8% share by volume<sup>5</sup>. Fabior competes in the US\$1.3b topical retinoid market in which 6m prescriptions are written per annum and has a 1% share by volume<sup>6</sup>. Sorilux participates in the US\$330m topical Vitamin D market with 1m prescriptions per annum and has a 3% share by volume<sup>5</sup>.

Favourable market dynamics have seen generic competitors launch against the key branded competitors to Doryx and Fabior. In recent weeks, one of these competitors has announced the restructure of its sales team which will reduce promotional efforts and share of voice. The Company is well positioned to take advantage of these market dynamics together with the second sales team and accelerate growth across the remainder of FY18.

I also want to highlight that earlier this month, Mayne Pharma filed a lawsuit in the US district court against Teva and Lupin for infringement of several Doryx MPC patents listed in the FDA's Orange Book with expiry dates in 2034. We are confident in the strength of our patent position and intend to vigorously defend the intellectual property rights of Doryx MPC.

## **Mayne Pharma International (MPI)**

Mayne Pharma International reflects Australian sales and revenue from the export of our products to international markets other than the US. This segment grew sales 12% to \$13m on the prior corresponding period. The stronger performance was driven by aspirin, itraconazole and doxycycline as well as the improved sales of injectables.

Pleasingly we recently launched Urorec® capsules, indicated for the relief of lower urinary tract symptoms associated with benign prostatic hyperplasia in adult men and we will launch Monurol® granules, used to treat urinary tract infections in females in December. We expect MPI sales and earnings will benefit from the launch of these two new chemical entities over FY18.

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<sup>5</sup> IQVIA IMS Health NSP MAT Sep 2017 and IMS Health weekly TRx data as at 17 November 2017

## *Brand pipeline*

The Company continues to progress the commercialisation of itraconazole globally for the treatment of certain fungal conditions and as a potential treatment for cancer. SUBA®-Itraconazole capsules are now sold in Australia, Spain and Germany as a treatment for certain fungal infections. It is also approved in a number of other markets and launches are expected in Argentina, Austria, Belgium, Columbia, Italy, Mexico and Portugal over the coming year.

There are now several highly encouraging clinical case studies being reported and published by Australian experts which are demonstrating the real-life product advantages of our product over the originator formulation in different patient groups.

SUBA-Itraconazole capsules are a patented formulation which has improved absorption and significantly reduced variability in blood levels achieved compared to the originator. These benefits provide enhancements to patients and prescribers enabling a more predictable clinical response as well as a reduction in the amount of active drug administered to deliver the required therapeutic blood levels.

In the US, the Company has successfully completed further pharmacokinetic studies to support the SUBA-Itraconazole anti-fungal NDA filing. The US anti-fungal triazole market has a current value of US\$520m<sup>6</sup> and the hospitalisation cost for histoplasmosis patients alone (one of the three first line indications for itraconazole) being approximately US\$370m per year in the US.

Our go to market planning is gathering pace and we currently expect to commercialise this product through our own sales team in FY19, targeting infectious disease specialists. Based on a clear unmet clinical need in serious systemic infections, the addressable market will be approximately US\$200m per annum, in which SUBA-itraconazole is expected to perform strongly.

In terms of the cancer program, HedgePath Pharmaceuticals Inc. (HPPI), which the Company has a 53% stake in, has completed enrolment of their Phase 2(b) trial in patients with a genetic form of skin cancer called Basal Cell Carcinoma Nevus Syndrome (BCCNS) – more commonly known as Gorlin Syndrome. HPPI continues to report the results of its open label study and in the latest data set they have measured the response of 477 individual target tumours, with 54% exhibiting a 30% or greater reduction in size since dosing began and 28% completely disappearing. Approximately 60% of lesions have continued to respond during ongoing treatment with a duration of response yet to be determined but currently exceeding one year at this point in time.

The patients on trial each had an average of 195 basal cell carcinoma tumours removed by prior surgeries, or a combined burden of 6,800 lesions prior to entering the trial. The

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<sup>6</sup> IQVIA IMS Health NSP MAT September 2017





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median time on study across all patients is 38 weeks, with 32 patients having been dosed for 16 or more weeks and 13 patients exceeding one year on therapy. While on study, only one target tumour in one patient has required surgical excision and 99% of target tumours are being controlled. These results suggest SUBA-Itraconazole provides an effective, safe and well-tolerated therapy to address the unmet medical need for non-surgical treatment.

Based on the clinical evidence described, HPPI is accelerating close-out activities for the BCCNS clinical trial and will file a pre-NDA meeting request during 2018.

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 and a further estimated 3,500 patients in western Europe. Pleasingly both the FDA and European Medicines Agency have granted SUBA-Itraconazole Orphan Drug Designation for BCCNS which provides certain benefits to a drug developer including a 7-year period of marketing exclusivity in the US and 10-years in Europe. In terms of the potential US market opportunity, the current total addressable market is estimated at US\$300m per annum<sup>7</sup>, based on an assessment of current healthcare costs to treat this patient population today due to the level of tumour burden in BCCNS patients.

So to conclude, while we have been facing some challenging trading conditions of late, Mayne Pharma has tremendous opportunities to deliver very strong growth in the second half and beyond. Our priorities haven't changed and we are focused on creating value for our shareholders through optimising our supply chain, exploiting new distribution channels, growing share of marketed products, bringing new products to market, accelerating growth of Specialty Brands through expansion of our dermatology sales force and further business development activity. Over the medium to longer term we expect to see further earnings diversification and rebalancing of our portfolio across our core business segments with a greater contribution from Specialty Brands, Metrics Contract Services and rest of world.

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.

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<sup>7</sup> HedgePath Pharmaceuticals investor presentation, October 2017