ASX Announcement

ANNUAL GENERAL MEETING

MINTER ELLISON
LEVEL 23, 525 COLLINS ST, MELBOURNE VIC 3000
AT 10.30 AM ON 27 NOVEMBER, 2014

CEO'S ADDRESS

Thank you Roger. Good morning Ladies and Gentlemen.

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

Roger has taken you through the highlights of the past financial year. I would now like to give you an update on how the business is performing at a sales level and how we are tracking with our key strategic priorities.

One of the key messages I would like to leave you with this morning is that as foreshadowed at the time of our full year results in August, MPI, our Australian-based business is being impacted by the manufacturing holiday we are facing on US Doryx™ tablets following declining prescription demand. Prescriptions continue to track around 5,000 scripts per week which is consistent with the levels we have seen over most of this year but well down on the peak levels we saw late last year prior to the sales force restructure that followed the acquisition of Warner Chilcott by Actavis. At this stage we do not expect to be manufacturing US Doryx™ tablets until sometime in the first quarter of calendar 2015 as inventory levels normalise to reflect in-market demand.

As a result of this, the Group's year to date revenue performance to the end of October was 14% weaker than this time last year (Group revenue of $38.1m vs $44.6m in the prior corresponding period (pcp). It is important to note that US Doryx™ sales accounted for 17% or $7.5m of the revenue to the end of October 2013, compared to just $0.1m in the four months to 31 October this year.

On a more positive note, excluding US Doryx™ sales, the remainder of the business is up on pcp and the Company expects the underlying business momentum in the two US-based businesses and the non-Doryx™ parts of the MPI segment to strengthen over the remainder of the financial year for a number of reasons which I will outline today.

The non-Doryx™ parts of the MPI segment are up 22% at a sales level on pcp with Lozanoc™, Astrix™ and the generic doxycycline and erythromycin products that were launched in the US driving the increase.

The US-based operations are in-line with last year at a sales level with Metrics Contract Services (MCS) up 13% and the directly-distributed US Products (USP) up 21%, but this good performance has been offset by underperformance with our third party distributed products such as Liothyronine and Oxycodone.

The drop in sales YTD for Liothyronine and Oxycodone has also resulted in a subsequent drop in the high margin royalties the Company receives from its distribution partners.

Liothyronine has faced increased competitive pressures following the launch of a new competitor into this market.

The third party Oxycodone franchise, which represented 15% of USP's sales in FY14 was just 3.5% of sales to the end of October. Following sustained poor performance by this distributor, the Company has served notice that it will begin distribution under its own label of the underperforming products which should deliver increased sales in the second half. These products participate in markets worth more than US$1.1 billion. Our Greenville operation is prepared for the increased production required to support our direct market entry.

In terms of the US Products that we distribute directly, the Butalbital combination product, which includes ZEBUTAL™, ESGIC™ and the multi-source generic version, was the strongest performing franchise this year, followed by the oxycodone unit-dose, erythromycin and amiodarone products.

In addition, the Company has recently launched two new generic products, Oxycodone HCl oral solution for the management of pain and Selegiline HCl tablets which are used to treat Parkinson's disease. Both products have had successful launches and new business has been secured.

Another challenge we have faced this year has been with our hydrocodone franchise, which includes LORCET™ tablets and the multi-source generic versions. These products have been subject to a change in the US DEA[1] classification, which has seen them reclassified as a Class II schedule drug, which imposes stricter requirements around distribution and labelling.

This change has affected the whole market, and we have now successfully addressed these new requirements and have just begun shipping new product after being out of the market for several months. Hydrocodone/APAP is the single largest oral solid product sold by volume in the US with over 7 billion tablets sold per annum and our products participate in a market worth more than US$600 million.

Hydrocodone and the oxycodone franchises represent the largest generic market opportunities for our Company in the near to mid-term. We plan to make these franchises material contributors to the US Products segment over the remainder of the financial year and beyond. Mayne Pharma is becoming a meaningful player in the large US opioid pain market through its expanding on-market portfolio and pipeline of products under development.

Metrics Contract Services, which provides formulation development and analytical services work for more than 100 clients, has performed well this year, with sales ahead of last year. The committed business pipeline continues to strengthen and the investment we made in new management and facilities last year is continuing to have a positive impact. The number of

[1] Drug Enforcement Agency

quotes signed is up 12% on last year and MCS has already introduced five new clients since the beginning of the financial year.

New research partnership with Flinders University

I am pleased to advise that Mayne Pharma has recently signed an agreement with Flinders University in South Australia to license intellectual property surrounding research relating to the use of Kapanol™, our sustained-release morphine product, for the treatment of dyspnoea, or shortness of breath. Currently, there is no medication registered for the symptomatic reduction of dyspnoea. Refractory dyspnoea is a prominent symptom amongst patients with advanced lung or heart disease. Research by Flinders estimates 1% of the population suffer from severe breathlessness[2]. In the US, this equates to 1.6 million potential patients. Refractory dyspnoea has significant unmet medical needs and our strategy is to collaborate with both government and academia to find an innovative treatment solution.

Mayne Pharma has obtained exclusive worldwide rights to past, present and key future clinical studies conducted by Flinders University on the treatment of dyspnoea and related intellectual property.

A research arm of Flinders University has already undertaken Phase II efficacy trials using Kapanol™ to treat refractory dyspnoea and found strong supportive evidence of a reduction in the incidence of breathlessness.

Further Phase III studies will be required to support any regulatory filing for this new indication. One such Phase III study is already underway with results expected in 2015, and a further trial has secured funding with a $1m grant from the National Health and Medical Research Council (NHMRC).

This program represents another example, alongside SUBA™-Itraconazole, of the Company's strategy to repurpose existing drugs where possible into new therapeutic fields.

Strategic priorities

The Company continues to make good progress in addressing its four near term strategic priorities.

Maximising the US retail generics business

The first is maximising the US retail generics portfolio by expanding the number of products on market and capturing fair market share for each product distributed directly.

Key to this strategy is control of the distribution and manufacturing of all of our US products where it makes sense. Currently, directly distributed products account for more than 70% of

[2] Severe breathlessness captures people who were too breathless to leave the house or stopped for breath after 100m or after few minutes on the level. A Community Population Survey of Prevalence and Severity of Dyspnoea in Adults, DC Currow, JL Plummer, A Crockett, AP Abernethy, Journal of Pain and Symptom Management, 2009; 38(4), 533.

US Product segment sales, up from just 10% two years ago. Wherever possible, the Company will bring third party distributed products in-house to maximise the margin generated.

To this end, in the second half of FY15, methamphetamine will be brought in-house under our label. In addition, there are several other third party sourced products in the portfolio where we are exploring our options to manufacture these products in-house to capture further margin.

Optimising the doxycycline franchise.

The second, but probably the most important near term strategic priority is optimising the branded and generic doxycycline products we market.

The US oral antibiotic acne market is currently valued at over US$800 million annually with doxycycline the key prescribed molecule for the treatment of moderate to severe acne. The addressable doxycycline market is worth over US$500 million or 2.7 million prescriptions written annually and comprises modified release products such as Doryx™ and immediate release products such as Acticlate™.

The Company is currently exploring a number of strategies to sustain and grow the doxycycline franchise. The current headwinds we are facing with US Doryx™ are short term only and we look forward to creating a more sustainable franchise that will deliver ongoing profitability and growth for our Company. I expect to be able to update the market with definitive plans in this regard early in 2015.

R&D execution

The third strategic priority is the successful execution of our R&D programme. I am very pleased with the progress we have made over the last year to advance our US and Australian pipelines. The total number of US filings jumped from 7 to 17 over FY14 and the addressable market for filed products is currently over US$1.8 billion. Our development groups in the US and Australia are actively working on a further 15 projects targeting addressable markets in the US worth US$4 billion in sales under the leadership of our new Chief Scientific Officer, Dr Ilana Stancovski, who is present here today and started with the Company in September.

As part of the development programme, we have filed a number of paragraph IV products with the FDA.

Under a paragraph IV filing, the generic or ANDA[3] filer seeks approval for a product with a listed patent and must certify the listed patent is invalid or will not be infringed by the sale of the generic drug. A 30-month stay may be granted before the FDA will approve the ANDA, pending outcome of any patent litigation.

The paragraph IV process provides an incentive for generic manufacturers as the first ANDA filed with the FDA that contains a paragraph IV certification is eligible, subject to prevailing in

[3] Abbreviated new drug application

litigation and FDA approval, to receive 180 days of market exclusivity during which the FDA is prohibited from approving subsequent ANDAs. For a generic company, being the first ANDA filer and achieving a period of exclusivity can be a very material event due to the efficiency of the US generic market which can see more than 80% of the brand volume switch to generics in the first 12 months.

Against this backdrop we believe we are the first-to-file an ANDA to Pfizer's Tikosyn® brand, and should this ANDA be approved and we prevail in litigation, we may be entitled to 180 days of generic market exclusivity. Tikosyn® is an agent used to treat irregular heartbeat with in-market sales today of US$150 million. The FDA has granted an expedited review for our product and a lawsuit has just been filed by Pfizer.

Paragraph IV proceedings typically take 30 to 36 months to resolve unless settlement is reached. The Company has also entered into an agreement with a development partner to share the litigation costs and potential profits from the sale of the product.

One further point I'd like to mention is the Company is not only active in patent litigation from a generic standpoint but is also actively protecting patents that have been granted on our products or drug delivery innovations. The Company currently has 12 patent families granted or pending in the US and we assert these patents where innovator companies have launched products that may infringe them.

One such example is an ongoing patent infringement lawsuit that Teva Pharmaceuticals, the world's largest generic firm, and our Company have filed against Forest Laboratories, now Actavis, over its Namenda XR® product which was launched in the US in June 2013. Our Company together with Teva contend the Namenda XR® product infringes a US patent owned by Mayne Pharma. The Company has granted Teva an exclusive license to enforce our patent in the US and under the terms of the agreement Teva covers all legal costs to pursue this action.

The Namenda® franchise had US sales of more than US$2 billion in the 12 months ended 30 September 2014. Teva and Mayne will share equally any proceeds from a successful action or settlement.

Although there are no assurances as to when such actions will be decided or the likely outcome, the Company will vigorously defend and enforce its legal rights.

In terms of approval times for our filed products, we have a very clear line of site in Australia but in the US we are still facing uncertainties due to the backlog of applications at the FDA. We remain confident that we will see more of our filed products approved in the coming year. In October, the FDA entered the third year of its government-mandated drug approval reform programme whereby its goal is to review 60% of original ANDA's submitted in this year within 15 months. The coming year will be critical to see if the FDA can in fact meet its review goals announced back in 2012.

Strategic acquisitions, licensing and partnerships.

Our final key strategic priority is to continue to broaden our portfolio both domestically here in Australia and the US through in-licensing activity or acquisitions. Our portfolio in Australia has more than doubled over the last year from 8 to 17 approved products. This portfolio expansion has come from in-licensing activity with a number of international specialty pharmaceutical companies.

In the US, we continue to search for synergistic product and enterprise acquisitions. On that front we recently signed an agreement to distribute another narcotic product, Hydrocodone-Homatropine syrup. The addressable market for this cough suppressant is approximately US$38 million with market launch likely to be in 2016.

Outside of Australia and the US, the MPI business exports its key branded products to numerous distribution partners around the world. As Roger mentioned earlier, we have grown our international footprint in the last year through out-licensing Lozanoc™ in parts of Europe and Asia. I am pleased to announce we have just agreed terms on two further out-licensing agreements.

We have reached an agreement in principal with ISDIN, S.A to expand our alliance for Lozanoc™ with the addition of Belgium, France and Germany and five Latin American countries, namely Mexico, Argentina, Peru, Columbia and Chile. ISDIN is already our partner for Lozanoc™ in Spain, Italy and Portugal and have been very pleased with the successful launch of Lozanoc™ in Spain earlier this year. The launch in other European countries will follow upon completion of the repeat-use procedure, which is currently underway.

The Company has also reached an agreement with Zuellig Pharma for the distribution of Kapanol™ in Thailand and we are working on finalising agreements for Kapanol™ in the Netherlands and Switzerland. All three countries have active Kapanol™ marketing authorisations and existing sales.

In closing, I would like to say that whilst we have faced difficult trading conditions in some parts of our business over the first few months of FY15 which have impacted our results compared to pcp, I am confident that we have taken the appropriate steps to deliver stronger sales and a greater earnings contribution in the second half.

Our business has enormous potential and we have a very exciting future ahead of us by taking control of our key products and franchises where it makes sense and continuing to execute our R&D program.

Thank you all for your ongoing support of our Company and I look forward to reporting on our progress in the coming year. I will now hand back to Roger to complete the formal part of the meeting.

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