



**ANNUAL GENERAL MEETING
MINTER ELLISON
LEVEL 23, 525 COLLINS ST, MELBOURNE VIC 3000
AT 10.00 AM ON 9 NOVEMBER, 2012**

CEO'S ADDRESS

Thank you Roger, Good morning Ladies and Gentlemen.

It is a pleasure to be speaking to you today at my first Mayne Pharma AGM. I am very excited and frankly honoured to have the opportunity to lead Mayne Pharma and return to the business where I began my career over 24 years ago.

Make no mistake, this business has enormous potential and I am very committed to pursuing both organic and inorganic growth opportunities and leveraging off our established product base, people, manufacturing facilities and technologies

We have a singular goal – to return this company to its previously held position as the leading Australian-owned specialty pharmaceutical company

With that said, I would like to now give you an update on how the existing business is performing, and then provide an update on the Metrics acquisition and plans for the integration of our businesses.

Firstly, our domestic sales operations which we call Mayne Pharma Australia.

Mayne Pharma is committed to building its domestic business in Australia through not only improving the sales and marketing of its existing proprietary products but also by in-licensing and acquiring attractive niche products with limited competition.

In Australia today, we sell 4 products – Astrix®, Doryx®, Eryc® and Magnoplasm®. Despite the age of these products we continue to enjoy solid growth in sales and profit contribution from this franchise. While protecting this backbone of legacy brands is important and a key focus area, we are very well placed as an attractive marketing partner for foreign companies who are seeking an independent local solution for distributing their products.

This was recently exemplified by Mayne Pharma entering into a strategic licensing and distribution agreement with Intas Pharmaceuticals for a range of injectable generic products for the Australian market.

Intas is one of India's leading pharma companies on the global stage, with world-class FDA, TGA and EMEA approved facilities and a deep pipeline of complex injectable products.

The agreement includes the rights to 11 existing injectable products targeting markets with \$73million in current annual sales and up to 30 pipeline injectable products targeting markets with \$140million in current annual sales. The pipeline products will be exclusive to Mayne Pharma and half of these products currently have no generic equivalent.

The Company has also just signed this week an agreement with a European specialty pharmaceutical company for the Australian rights to exclusively market and distribute a niche cardiovascular injectable generic product. Mayne Pharma expects to file this product with the TGA during the 2013 calendar year. The current market sales for this product are \$2.5m (IMS Health, MAT June 2012) and growing at 10% per annum with no generic competition.

These recent developments in the domestic business follow the appointment of Peter Truelove as the National Sales and Marketing Director who has a proven track record of sales leadership and success in both the branded and generic segments of the Australian pharmaceutical industry.

In addition, we have also just appointed Mr Stefan Cross as Vice President of Business and Commercial Development responsible for all in-licensing and out-licensing activities. I have previously worked with Stefan and he brings a wealth of international and domestic pharmaceutical experience to the Company. I am certain that he will play a key role in executing our business strategy, leading our partnership negotiations and further accelerating the growth of our domestic business.

Following completion of the Metrics acquisition, the company will be filing more than 10 products in calendar 2013 with the TGA. These include SUBACAP®, a number of injectable products and potentially several Metrics products. In short, we are well positioned for growth in this important segment of our business, and following approval by the TGA these products are expected to lead to significant revenue and margin uplift of the Mayne Pharma Australia business segment in the mid-term.

Turning now to Out-licensed sales, or products which we manufacture and sell to international distributors

Our most significant product today is Doryx® which has been impacted this year by the launch of a generic version in the United States. We are keeping a close track on prescription volumes which is an indicator of underlying demand, and are pleased to report that prescription volumes have been stable now for four months from July through to late October at approximately 5,000 new scripts a week and over 8,500 total scripts a week.

This underlying demand represents a 35% fall from pre-generic volumes, which is at odds with a typical US generic substitution curve, which can see the branded product lose at least 80% of volume very quickly following a generic event. The successful defence of this franchise has been driven by Warner Chilcott maintaining its full Doryx® sales force and customer loyalty card program.

While we are very happy with the defence of Doryx®, the first half of this financial year has been significantly impacted by reduced shipments of Doryx® resulting from de-stocking of the distribution channels. We do, however, expect normalisation of supply to occur in the second half of FY13, albeit at reduced volumes, reflecting the loss of market share.

In summary, the doomsday scenario has not happened. This is not a surprise – it was planned, and we are very encouraged by Warner Chilcott's continuing commitment to the Doryx® franchise, whether that be supporting the current product or pursuing the introduction of new versions of Doryx®.

In terms of the balance of the out-licensed portfolio, we are seeking to internationalise further the Mayne Pharma portfolio which is currently only sold in 10 countries in aggregate today and the Metrics' product portfolio which is currently only sold in the United States. I hope to be able to provide concrete examples of this growth platform in coming months.

Research and development

Moving to research and development, the key driver of sustainable growth and value in our company.

I am pleased to report that we are nearing completion of the regulatory procedure for SUBACAP® in Europe. SUBACAP® is an improved version of the anti-fungal agent, itraconazole, used to treat both superficial and systemic fungal infections. The SUBACAP® dossier was lodged in Europe with the reference member state, the UK, two years ago. In June 2012, the UK advised that the product was now approvable subject to some minor amendments.

We have subsequently received feedback from the other concerned member states - Germany, Spain and Sweden – who concur with the UK. At the end of October, we submitted amendments to the dossier which addresses the questions raised through the procedure. It is important to note that the original clinical concerns from December 2011 have now been overcome.

We are expecting the procedure to conclude next month, following which national approvals to market SUBACAP® in Germany, Spain and Sweden will follow.

In parallel with completing the regulatory procedure, the Company is engaging with a number of regional and global pharma companies who have shown interest in the product. We hope to enter into suitable marketing and distribution arrangements over the coming months with a select partner(s).

Following closure of our current European procedure we plan to file the product in at least 6-8 other European countries via an accelerated 'repeat-use' procedure. Our expectation is that 10-12 European countries will be approved for SUBACAP® during 2013, with these countries representing more than 80% of the current US\$85 million in annual sales of itraconazole across Europe.

In the United States, the Company met with the US Food and Drug Administration (FDA) anti-infective products division earlier this week to discuss the regulatory pathway for SUBACAP®. Following this meeting, the Company believes there may be an alternate pathway to market that may obviate the need to perform an expensive and time-consuming Phase 3 clinical study. We are proceeding to confirm the exact requirements with the FDA, and we will report back in due course, however, we have the potential to materially reduce time-to-market.

Lastly on SUBACAP®, we plan to file marketing applications in Australia and Korea next year and accelerate commercialisation of SUBACAP® in Japan – the worlds largest itraconazole market - and select other South American countries.

Moving to other R&D projects.

As you may be aware, the Company introduced two new projects into R&D earlier this year. The first program is an extended release pain product targeting a US market with annual sales of \$270million, (IMS Health 2011). We are now in the process of transferring this technology to one of the world's largest drug delivery companies in the US. We will be commencing our pivotal biostudy during 2013 and anticipate filing the product with the FDA before the end of the year.

The acquisition of Metrics will significantly de-risk the pain program by providing on-the-ground formulation, analytical and project management support during the development stage.

Following FDA approval, Metric's will sell the product directly to wholesalers and retail pharmacy chains, which, importantly, enables the Company to capture full value that would otherwise have been partly ceded to a third party distributor.

The other project that is under development is a pellet-in-a-tablet formulation used to treat high blood pressure and targeting a US market with annual sales greater than \$1 billion. We are approximately 1 year behind the pain program in terms of filing. We expect that the acquisition of Metrics will enable us to capture full value from commercialisation of this product as well as several other tier 1 candidates we identified during our R&D review earlier this year.

I intend to update you on the Metrics deal in a minute, but it is worthwhile mentioning that at the beginning of 2013 the Company had one product in development. Today, and with addition of the Metrics business, the Company will have 16 products in active development. Our success in progressing this pipeline to market, including the expansion of this pipeline, will deliver improved returns to our Company.

Metrics acquisition

I will now provide an update on the Metrics acquisition which we announced just over 1 month ago. Completion of the acquisition will occur following settlement of the conditional placement shares next week, assuming we receive the requisite shareholder approval today.

I firmly believe the acquisition of Metrics is going to be extremely exciting and positive for Mayne Pharma and will deliver ongoing profitability and growth in shareholder value.

Until now, Metrics has been a privately owned, US based provider of contract development services to the pharmaceutical industry with its own portfolio of niche generic products. Metrics was founded by the current management in 1994, and began as a start up analytical laboratory before moving into formulation development, and then clinical and commercial manufacturing.

Metrics has been one of the fastest growing pharmaceutical contract development and manufacturing organisations in the US over this time. Today the contract services business has over 100 clients including big pharma as well as smaller biotechnology companies. In 2004, due to the success of the contract services business model, Metrics made a strategic decision to move into developing its own generic products.

To develop this business Metrics appointed Richard Moldin, a previous FH Faulding & Co senior executive who has an outstanding track record in the US generic industry. Richard and I worked together to develop the Purepac generic business in the US for many years, which subsequently became part of Alpharma and then Actavis. Richard has been instrumental in developing the Metrics' pipeline and commercialising their portfolio, and he will continue to drive the business forward post closing. As a result of the success of the generics business, Metrics has doubled its R&D spending over the last 2 years to more than 12% of sales and is planning to file up to 9 products by the end of 2013.

Metrics' technical capabilities encompass expertise in formulating complex oral dose forms including highly potent compounds such as cytotoxics, controlled substances (such as opiates) that cannot be imported into the United States, together with inherently unstable compounds and products with poor bioequivalence.

Of the 9 current approved products, 4 of these products were the first generic approvals in the US market and two of these products Liothyronine (to treat hypothyroidism) and Methamphetamine (to treat ADHD) maintain a number 1 market share position.

This track record of success is a testament to the quality of the analytical chemists, formulation scientists and other support staff in the business.

The Metrics pipeline is focused on bringing to market generic products, which are niche, small or difficult to formulate with limited competition. Metrics' business model has enabled it to be nimble and faster to file than its competitors and receive accelerated pathways for FDA approvals. Metrics intends to continue to introduce 5 to 6 new products to the development pipeline each year.

In terms of an update on the Metrics business, I have only just got back from a visit to the site last week and wanted to let you know about some of the more recent developments:

- Metrics senior management and the operating team are very excited about the opportunity of combining these two very complementary businesses. They are particularly interested in the Mayne Pharma development pipeline and working with our team on accelerating the commercialisation of these products in the US.
- In terms of the product development pipeline, a further two products have been put into development including an eye drop to treat allergies and an osteoarthritis topical gel targeting US\$200 million in annual sales. These products will expand the Metrics pipeline of new products to 13 in development targeting markets with over US\$2.0 billion in annual sales.

In terms of the integration of the two businesses, we will be setting up project teams across a number of functional streams. The key focus areas in the short term will be finance and IT, regulatory, business development, HR and research and development.

The key identified revenue generating projects will be:

- Cross selling Mayne Pharma's approved and pipeline products in the United States
- Cross selling Metrics products in Australia and through Mayne Pharma's distribution partner networks in Europe and Asia
- Acceleration of Mayne Pharma and Metrics' development pipeline
- Leveraging Metrics contract services customer base to identify opportunities to in-license in Australia

That concludes my update on the business. In closing I would like to thank you all for your ongoing support of our Company and I look forward to reporting to you on our progress in the coming year. I will now hand back to Roger to complete the formal part of the meeting.