ANNUAL GENERAL MEETING

MINTER ELLISON
LEVEL 23, 525 COLLINS ST, MELBOURNE VIC 3000
AT 11.00 AM ON 26 NOVEMBER, 2014

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 and give you an update on how our company is performing and our key strategic priorities.

Our Company is certainly in a very different position to where it was twelve months ago and I am pleased to report that the financial performance and position of the Company has been transformed as a result of the actions we have taken over the last year. By acquiring Doryx™ and bringing in-house the distribution of this product, and taking control of the oxycodone franchise, we have significantly improved both the top line and bottom line. Our year to date performance to the end of October certainly shows this with revenue up 120% on the prior corresponding period (pcp) to $84m and group gross profit margin has improved materially on pcp.

With the acquisition of Doryx™, the Company expanded its US operations and now has 3 distinct and complementary operating segments - Metrics Contract Services, Specialty Brands and Generic Products. These three businesses represented 88% of group revenue in the first four months of FY16.

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

Specialty Brands Division (SBD)

Starting with the Specialty Brands Division or SBD. This business was established earlier this year following the Doryx™ acquisition and is responsible for the sales, marketing and distribution of branded pharmaceuticals. The key focus for this business in the near term is to reinvigorate the performance of Doryx™ in the US dermatology market. Over time we expect to expand our portfolio in dermatology and other attractive specialist-driven therapeutic areas via organic development and select product licensing or acquisitions. Our improved formulation of itraconazole is one such product that would leverage SBD's commercial infrastructure in the future.

In terms of the in-market performance of Doryx™, the 200mg product continues to be holding steady with prescriptions being maintained at around 4,800 scripts / week. The 50mg product which was launched in August is tracking around 600 scripts / week and growing. Doryx™ has held onto its market share through the change in ownership from Actavis – outperforming our expectations set at the time of completing the transaction - and we are confident that we can expand market share over time by improving sales force effectiveness.

In terms of SBD's financial performance, the first four months of sales are in line with the expectations we set back in February and we also continue to forecast that Doryx™ will deliver the earnings guidance we gave at that time of US$2.7m of EBITDA on average per month during FY16.

Generic Products Division (GPD)

Moving to the US Generic Products Division or GPD. Year to date sales are up more than 40% on pcp in USD terms and 65% in AUD terms driven by our key product franchises such as oxycodone, BAC, hydrocodone, methamphetamine, doxycycline, erythromycin and amiodarone. Market share gains and pricing improvements, and the capture of the full profit margin on oxycodone and methamphetamine are the key drivers of growth of these franchises. Nine of the top 10 molecules grew net sales and increased unit market share over the last year. In terms of sales, oxycodone is now our number 1 generic franchise and includes a number of different dose formulations and strengths. On the downside, Nystatin has continued to face greater competitive pressure following launches by new competitors.

Liothyronine, our one remaining 3rd party product has returned to growth driven by the improved performance of our distributor Perrigo, with a leading edge quarter on quarter volume growth of 6%.

Other highlights in this division include the launch of BAC tablet in August and the recent approval of BACCP (butalbital / aspirin / caffeine / codeine phosphate) capsule. The BACCP product had market sales of US$40 million for the 12 months ending 30 September 2014 according to IMS Health with three current competitors. We expect to launch this product shortly.

We have also recently strengthened the US leadership team with the appointment of Craig Boyd as Executive Vice President of Generic Products. Craig brings more than 20 years of industry experience across generic, branded, biosimilar and device businesses and has worked extensively in the US, Europe and Australia. He was previously the head of sales for Pfizer's US generic injectables division with revenue of over US$4bn and more than 300 staff. Craig was also previously the Vice President of Global Sales at Mylan, one of the world's largest generic pharma companies leading sales teams across all international markets.

Metrics Contract Services (MCS)

The final US segment, Metrics Contract Services, or MCS, is our fee-for-service business offering more than 120 clients an array of services from analytical chemistry to formulation development. This business has also had a strong start to the year with revenue up more than 20% on pcp in USD terms and 38% in AUD terms. All key performance measures are trending favourably with quote value won up on the prior year and the committed business pipeline revenues continues to grow at double digit rates.

Growth in this business is being driven by significant improvement in our commercial and analytical services and formulation development operations, together with favourable market conditions, which are especially strong for early stage pharmaceutical development work.

Mayne Pharma International (MPI)

The final business segment is Mayne Pharma International or MPI. Following the segment change this year, MPI no longer captures any margin from US Doryx™ sales or the doxycycline and erythromycin authorised generic sales, which are now reported by SBD and GPD respectively.

MPI's sales revenue reflects domestic sales and revenue from the export of our products to international markets other than the US.

The Australian business is benefiting in FY16 from the addition of several new products. Oxycodone tablets, an original Metrics product was launched this year as the first independent generic to Endone. We also are seeing more revenues from our injectable product range and recently received approval for Noradrenaline, which will be the first generic competitor in this market and will be launched early next year.

Outside the US and Australia, Lozanoc™ and Kapanol™ continue to be growth franchises for the business offset by Astrix™ which is currently underperforming in Korea due to reduced in-market demand following pricing changes.

Investing for growth

As Roger mentioned earlier, your Board and management team are committed to building this business globally and investing for growth is fundamental to building a sustainable specialty pharma business.

In the last 3 years, we have invested $50m in research and development and we expect to spend more than $25m in this financial year. Our R&D program is focused on pursuing projects with intrinsic barriers to entry which we believe we have the capability to address. To that end, the portfolio of products under development includes a diverse array of highly potent products, semi-solid liquid and cream products, controlled substances and products that utilise our advanced drug delivery technologies such as SUBA and multi-particulate controlled release. We believe our R&D strategy will deliver superior returns to shareholders over time.

Today, we have more than 30 US pipeline products targeting markets with sales of more than US$7bn and a further 20 Australian pipeline products targeting markets with sales of A$150m. In the US, we have 16 products pending approval at the FDA targeting addressable markets with sales greater than US$1.9bn. Of the 16 pending products, 6 products have been filed with the FDA for more than 2 years, 1 product has received expedited review as a paragraph IV product and 3 products have received 2016 target action dates, as they were filed with the FDA recently.

The most significant of our filed products is our generic version of Pfizer's Tikosyn used to treat irregular heartbeat. This is a paragraph IV product and following the settlement of our litigation with Pfizer we expect to launch our generic version following FDA approval and ahead of patent expiry. It is also important to note we expect to be awarded 180 days of generic market exclusivity as it is a first to file paragraph IV ANDA. The Tikosyn product has annual in-market sales today of more than US$170m and according to IMS reports it grew 15% in the last 12 months. In terms of approval time, we are in active dialogue with the FDA on this dossier and expect to launch in calendar 2016.

Over the last 3 years, the Company has invested more than 80% of its R&D in generic programs with the remainder invested in advancing our pipeline of branded products, which includes next generation Doryx™, our anti-fungal Lozanoc™ product and the repurposing of our SUBA-Itraconazole product into cancer through our alliance with HedgePath Pharmaceuticals. The Phase IIb clinical trial in patients with Basal Cell Carcinoma Nevus Syndrome - or commonly known as Gorlin's Syndrome - has commenced and we have already dosed a number of patients. The trial is still at an early stage but we expect preliminary results in early 2016.

As Roger mentioned we are in the process of significantly expanding our facilities both here in Australia and in the US to support our business in the mid to long term. These capex programs will support growth of on-market products, the commercialisation of our pipeline and the expansion of our contract services business, thereby offering multiple sources of value. I strongly believe that controlling our product supply chain wherever possible will deliver considerable strategic value to the company in terms of customer service levels, reducing business continuity risk, protecting our intellectual property and reducing cost.

So, in summary your Company has established an outstanding platform for accelerating growth in highly attractive segments within the world's largest pharma market, and to that end your management team is committed to pursuing both organic and strategically compelling inorganic growth opportunities to further advance the company's strategy.

That concludes my update on the business. In closing I want to thank you all for your on-going support of our Company and I look forward to reporting on our progress across the coming year. I also want to thank our 600+ staff. I am proud of the team we have assembled and the growth potential our talent creates. I will now hand back to Roger to complete the formal part of the meeting.