ASX Announcement

2019 ANNUAL GENERAL MEETING

INTERCONTINENTAL MELBOURNE, THE RIALTO
495 COLLINS ST, MELBOURNE VIC 3000
AT 10.00 AM ON 22 NOVEMBER, 2019

CEO'S ADDRESS

Thank you, Roger. Good morning Ladies and Gentlemen.

Today I will provide you with an update on our strategy and key priorities to rebalance our portfolio, our trading performance in the first four months of this fiscal year, an overview of the novel, next generation oral contraceptive product E4/DRSP that we recently licensed and finally comment on our outlook.

As Roger outlined earlier, the US generic market continues to have challenging dynamics driven by the aggressive contracting behaviour of the three major buying groups that control circa 90% of retail generic drug purchasing. These dynamics have driven heightened levels of price deflation over the last few years that have been well documented. From its peak in 2016, the US generic market has declined by around US$12b or 18% at manufacturer level and this impact can be seen in the softer results reported by many of our US peers over the last two years[1].

At a macro level there are signs of stabilisation appearing in the generic market with reduced R&D spending leading to fewer applications being submitted to the FDA. We also see major generic pharmaceutical manufacturers closing plants, restructuring their operations and withdrawing unprofitable product lines. For example, Teva has announced closure of 15 plants, Mylan has discontinued 350 SKUs and both organisations have announced significant reductions in their global workforces impacting more than 15,000 people and materially reducing their scope of R&D activities.

Whilst we have attractive near to mid-term opportunities in the generic market through new product launches, taking advantage of competitor withdrawals, expanding alternate non-retail channels and improving our supply chain and cost base, we continue to focus on reshaping our business towards branded therapeutic segments and associated distribution channels that we can leverage to develop better protected and more sustainable revenue and profit streams. This is no better evidenced than by our recent deal where we secured exclusive US commercial rights to a novel, next generation oral contraceptive E4/DRSP that we believe will transform Mayne Pharma in the medium term.

[1] IQVIA, NSP MAT September 2019

Our generic business of course remains an important feature of Mayne Pharma, however the prevailing buy-side dynamics in this sector combined with our deeper commitment to our specialty products platform demands that we reduce our allocation of capital to our generics franchise, to drive more sustainable value creation for our shareholders. Our generic business will continue to access and introduce new products going forward, however our focus will be on product categories and associated distribution channels where we believe revenue streams and returns are more predictable.

In summary, our strategic priorities include driving share growth of our on-market products, broadening our branded specialty portfolio through focused R&D and business development activities, leveraging our commercial footprint and expertise to develop more effective distribution channels for both our branded and generic products, and optimising our cost base through productivity improvements as our young company continues to mature.

Moving to the results for the first four months of FY20.

Group revenue to the end of October was $154m, down 16% on the prior corresponding period (pcp). Whilst disappointing, this was consistent with revenue in the first four months of this calendar year (Jan-Apr 2019). These results reflect additional competition on our key generic products – liothyronine and dofetilide – that we have previously reported to the market.

Our group gross margin has been impacted by our changing product sales mix and inventory obsolescence in generics. We are tightly managing our operating and R&D expenses across the organisation as we foreshadowed at our full year results in August and have achieved a $4m or 7% cost reduction in the first four months of this fiscal year versus last year.

Generic Products Division (GPD)

Generics Products Division revenue was $89m in the first four months of FY20 down 26% on pcp, however this was flat on the first four months of this calendar year (Jan-Apr 2019). Liothyronine and dofetilide contributed to the majority of the decline versus pcp.

Mayne Pharma continues to realign its generic business focusing investment activities in the core therapeutic categories of women's health and dermatology. This year the Company has licensed three dermatology products to leverage the unique sales and distribution capability we have established and is in active discussions with a number of third parties around further product collaborations. Two of these in licensed dermatology products - generic LOICOID® lotion and generic CORDRAN® ointment – are expected to launch next month.

In women's health, we continue to optimise this portfolio and are actively transferring a number of products to new contract manufacturers to extract cost savings. The women's health portfolio represents a quarter of GPD sales and grew 50% on pcp at the gross margin line in the first four months of this fiscal year. Our women's health pipeline includes three contraceptive products with no generic equivalents today targeting markets with sales of more than US$1.1b. The most significant pipeline product is the company's filing of generic NUVARING®, the largest contraceptive product sold in the US which is targeted for approval in CY20.

Metrics Contract Services (Metrics or MCS)

Metrics Contract Services, our fee-for-service business grew revenue 16% in the first four months of FY20 to $26m benefiting from additional analytical services and formulation development revenue. This business has a strong track record of growth outperforming market growth rates through strong retention of its customer base, a track record of scientific and technical excellence, and the strategic investments made in Greenville in new technology and manufacturing capacity.

Metrics is one of a few US based potent solid oral dose CDMOs with a single site that can handle early stage development work through to commercialisation. Metrics has a diverse and high-quality customer base that includes around 100 active customers including 7 of the top 15 global pharma companies.

In 2019, Greenville successfully passed inspections by the FDA, Japanese PMDA and the European EMA which are key steps for Metrics to become a global supplier of pharmaceutical products. The Greenville plant has been steadily growing its throughput with monthly average commercial batch volumes increasing from 27 in FY18 to 45 in FY19 and this year is tracking at 68 in the first four months of FY20 which is almost double the pcp.

Across the first half, we expanded Metrics' scientific workforce to support the growing pipeline of committed business. The pipeline of commercial manufacturing opportunities remains solid and is expected to be a key growth driver over the coming years. Metrics is expected to have five commercial manufacturing clients in FY20 with three of these expected to launch their Greenville manufactured products in the second half.

Specialty Brands Division (SBD)

Specialty Brands Division revenue was $26m in the first four months of FY20 consistent with the prior period. SBD results were lower than expected, with DORYX® and SORILUX® sales down on the prior period impacted by new competitor launches offset by sales growth from our two new product launches this calendar year – LEXETTE®, a corticosteroid foam to treat plaque psoriasis and TOLSURA® (SUBA-itraconazole) capsules used to treat systemic fungal infections.

The overall doxycycline delayed-release prescription market was down ~20% on the prior year impacted by the recent launch of a new tetracycline antibiotic for treating acne. The DORYX franchise remains the largest and most mature product family in the specialty portfolio and whilst sales were down on pcp, the product mix has improved from a scrip profitability perspective.

Leading edge demand as measured by dispensed prescription data show the DORYX family rebounding in September and October benefiting from changes to our patient co-pay card offering, with prescriptions up 20% in October from an all-time low in June[2]. SORILUX is also seeing a rebound in prescriptions in October with the highest monthly rate since May 2019.

LEXETTE, a new foam formulation of halobetasol was launched in February and is tracking close to 900 prescriptions in the latest week of data. The 3QCY19 LEXETTE prescriptions were up 15% on the 2QCY19. We expect to see further growth from this product over time as it takes share of the ultra-potent steroid market.

The launch of TOLSURA has allowed Mayne Pharma to establish a new institutional commercial platform with sales, account management and medical personnel calling on infectious disease and pulmonology physicians. In FY20, TOLSURA has been listed on 6 major hospital network formularies representing 11% of the institutional itraconazole market reported volume. These accounts represent a key prescriber base which will support ongoing expansion nationally. We are seeing more formulary wins each month and a steady increase in the prescriber base and new patients.

We expect TOLSURA to be a key growth product over the next few years and this new institutional platform has the potential to springboard Mayne Pharma into additional therapeutic categories through follow-on R&D investments to expand the clinical use of TOLSURA and complementary business development activities. We see the immediate addressable market for this product at around US$300m including systemic fungal infections and select other indications and expect TOLSURA to capture at least 25% volume market share of the itraconazole market by the end of FY22.

[2] IQVIA, TRx 8 November 2019

Mayne Pharma International (MPI)

Mayne Pharma International sales were $13m in the first four months of FY20 down 7% on pcp impacted largely by reduced commercial manufacturing revenues. MPI remains focused on growing its higher margin formulation development services and specialty brands portfolio globally.

E4/DRSP oral contraceptive

I would now like to make a few comments on the transformative deal we recently completed to exclusively license the novel contraceptive product E4/DRSP from Mithra Pharmaceuticals (Mithra) to commercialise in the US.

This transaction is highly consistent with our strategy to build our business with durable high growth products in core therapeutic categories such as women's health leveraging our commercial capability and associated know-how in the US. This product is expected to be a foundation branded women's health product and has a strong and synergistic fit with our currently marketed portfolio of 20 branded generic contraceptives and pipeline products such as generic NUVARING.

E4/DRSP is a next generation combined hormonal oral contraceptive comprised of Estetrol, or E4, and the progestin, drospirenone, or DRSP. E4 is a native estrogen produced by the human foetal liver during pregnancy and if approved would be not only the first native estrogen approved in the US but also the first new estrogen introduced for contraceptive use in the US in approximately 50 years. Following more than 20 years of research and development, Mithra can now produce E4 at scale through a complex plant-based production process.

This innovative contraceptive product has a unique mode of action that phase 2 and phase 3 studies suggest could result in improved patient outcomes. Mithra has completed two phase 3 studies in more than 3,700 patients with positive top line results against efficacy and safety endpoints and achieved secondary endpoints including good bleeding profile, cycle control and tolerability.

E4/DRSP will compete in the short-acting US contraceptive market in which more than 10 million American women use combination (estrogen + progestin) oral pills, patches or vaginal rings each day. This combined hormonal contraceptive (CHC) market is valued at US$4b with the top two brands being NUVARING contraceptive ring with US$970m in sales and LO LOESTRIN® FE with US$830m in sales[3].

We have high expectations for E4/DRSP which is expected to launch in the first half of calendar 2021, subject to FDA approval with peak net sales potential of more than US$200m per year.

[3] IQVIA NSP MAT Sep 2019

Outlook

As you know, in the last few years our results have been volatile due to the many factors that can impact performance in any period such as the timing of FDA approvals, competitor launches and withdrawals on key products. In light of this, Mayne Pharma does not give earnings guidance.

Mayne Pharma's longer-term outlook has improved significantly over the last year following the approval and launch of TOLSURA, and the licensing of the novel oral contraceptive E4/DRSP. Our company also has many other opportunities for near and long-term growth.

The most significant near-term opportunity is the launch of generic NUVARING. The Company has been working closely with Mithra, our development and manufacturing partner on FDA questions which are expected to be submitted by the end of this calendar year. To date there have been no generic approvals and through public disclosures we understand several possible competitors have experienced further delays in their programs.

In addition to NUVARING, Mayne Pharma's generic pipeline includes more than a dozen products pending at the FDA and in late stage development, including several complex generics and four products with no generic equivalents today. We hope to bring several of these products to market by the end of calendar 2020.

Over the medium term we have two significant specialty brand projects in phase 2 and phase 3 development. The Company continues to progress the commercialisation of SUBA-itraconazole as a potential treatment for certain cancers. A phase 2 trial has been completed in 38 Basal Cell Carcinoma Nevus Syndrome (BCCNS) patients and demonstrated that SUBA-itraconazole was well tolerated with the majority of target lesions decreasing in size. A global phase 3 pivotal trial is expected to commence in the new year in moderate to severe BCCNS patients.

In August, the Company commenced a global phase 2 study with trifarotene in 120 patients with lamellar ichthyosis. Congenital ichthyosis is an orphan disease causing severe skin scaling that manifests through the first weeks of life and lasts a lifetime with multiple impacts including disability, partial deafness, severe discomfort and psycho-social impacts. There are no treatments approved by the FDA for moderate or severe subtypes of this disease. It is also worth noting that our partner, Galderma, recently received US FDA approval for a different strength of this drug in acne. We see this as a positive development for our program.

We hope to successfully commercialise both these products over the coming years and improve the quality of life for the patients with these serious skin diseases.

In addition, we also expect growth in our women's health portfolio of branded generic contraceptives and our generic and branded dermatology product portfolio. Our contract service business is expected to benefit from new commercial manufacturing revenues from a number of client NDA launches expected across calendar 2020.

As I mentioned earlier, we are carefully managing our expense base and expect to see operating expenses decline further and more normalised levels of stock obsolescence in the second half of FY20. Over the medium term, we expect to realise material cost savings and benefits from product transfers in-house or to new contract manufacturers and through achieving greater operational efficiencies in our manufacturing network.

Finally, I would like to thank the Board, the leadership team and all our employees for their hard work, commitment and passion. I am confident the changes we have made this year have positioned the business for a stronger future.

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