



## 2020 ANNUAL GENERAL MEETING

AT 10.00 AM ON 24 NOVEMBER 2020

### CEO'S ADDRESS

Thank you, Roger. Good morning to you all from North Carolina.

I will start by giving a brief update on the business and our key priorities and then finish with our trading performance for the first four months of this fiscal year.

First of all, I would like to acknowledge the impact that COVID-19 has had on our business and our people. While this remains a deeply challenging situation in the US and has added complexity to our operating model, I am pleased to report that we are navigating this environment well. We have adapted our work practices to ensure the safety of our employees whilst maintaining morale, productivity and output. We have also adapted to a new type of engagement with our customers, doctors, pharmacists and patients and we continue to look for more innovative and effective ways to better run our business as we hopefully emerge from this public health crisis in 2021.

Our key growth priorities remain consistent with our last market update – that is, preparing to launch our novel oral contraceptive, NEXTSTELLIS® (E4/DRSP), expanding our dermatology and women's health portfolios, driving growth of our branded anti-fungal TOLSURA® (SUBA-itraconazole), accelerating our global contract services platform and optimising our cost base.

NEXTSTELLIS (E4/DRSP), is the Company's most significant near-term pipeline opportunity. The product is a novel oral contraceptive which contains a new estrogen called Estetrol or E4 in combination with a progestin, drospirenone. If approved, E4 will be the first new estrogen introduced in the US for contraceptive use in 50 years. E4 is a low-impact estrogen with a unique mechanism of action that offers potential advantages over other estrogens used in contraception. The Company's strategic development partner, Mithra Pharmaceuticals, has studied this product in more than 4000 women in Phase II and Phase III trials. The phase III trials met efficacy end-points and demonstrated good bleeding control – which is a clear expectation of women using an oral contraceptive. Further, a phase II trial importantly showed a favourable effect on certain markers associated with blood clotting, which is one of the known risks with many contraceptives. NEXTSTELLIS has also shown a neutral effect on weight gain. Being a native estrogen, NEXTSTELLIS has the potential to have a lower adverse impact on the environment and this could also be a key differentiator against other contraceptives on the market today.



## ASX Announcement

Mayne Pharma has the distribution rights for NEXTSTELLIS in the US and Australia. The product is currently pending at a number of regulatory agencies around the world including the US, Europe, Canada and Australia. In September, we had a mid-cycle review meeting with the FDA and we were pleased that no substantive issues and no major safety concerns were raised. We have another important meeting with the FDA in early 2021 at which time we expect clarification on all major review matters as we close in on our target action date set in April 2021.

We also continue to advance our pre-launch awareness education with thought leaders and prescribers and associated launch planning. To that end we have broadened our leadership team to support NEXTSTELLIS with Mr Don Pearl joining us as Executive Vice President (EVP) Women's Health. Don brings almost 30 years of highly relevant industry experience including leadership of significant US brand commercial businesses and importantly the establishment of new sales and marketing organisations through launch phase.

The second key priority for the business is to continue expanding our product portfolio through selective licensing and partnering activities. Given Mayne Pharma's scale and differentiated commercial infrastructure, we are well positioned to add additional products in an efficient manner. In women's health we recently added five branded generic oral contraceptive products through the Novast Laboratories supply agreement. Four of these products are already approved and are expected to launch in the coming months, including versions of the top two prescribed contraceptive products in the US – ORTHO CYCLEN® and ORTHO TRI-CYCLEN®. We recently licensed a new brand SOLTAMOX® (tamoxifen) oral solution which is indicated for the treatment of women with estrogen receptor-positive metastatic breast cancer and prophylaxis for women at high risk of breast cancer. This product will be promoted digitally until our new women's health sales team is in place.

We have a number of dermatology and women's health products pending at the FDA. As Roger mentioned, the recent delays in two of our key generic programs have been frustrating and we are working hard with our partners to address the FDA's questions. In one of the programs, the FDA found all key disciplines of the ANDA adequate with the exception of the packaging facility. In the case of our generic version of NUVARING®, we expect to submit our response to the FDA in the new year after which we will receive a new target action date. Both these new product opportunities remain highly attractive with limited competition.

Our earlier stage pipeline programs include the novel retinoid trifarotene to treat patients with lamellar ichthyosis which is a rare dermatological disorder that causes severe skin scaling from birth. There are no approved treatments for this condition. We have recruited 41 patients into the phase II clinical trial with top line results expected in FY22.



## ASX Announcement

We continue to remain confident about the potential of TOLSURA<sup>®</sup> (SUBA<sup>®</sup>-itraconazole) and its ability to capture a meaningful share of the itraconazole market over time. This product has faced challenges this year from COVID-19 as the product is typically prescribed by infectious disease and respiratory physicians who are heavily involved in the pandemic. Our belief in this product is driven by a growing body of scientific data supporting its clinical attributes. Most recently, the Company reported its initial results in the ongoing endemic study which is the largest clinical study in 30 years in patients with various endemic fungal infections in the US such as histoplasmosis and blastomycosis. Data from this study was recently presented at IDWeek 2020, the largest conference in the infectious disease space and has been well received. New prescriptions were at their highest level in September since we launched the product, and were up 30% on the pre COVID monthly volumes in the first quarter of this calendar year

Mayne Pharma's contract services business is sometimes described by investors I speak to as an under-appreciated asset within Mayne Pharma. CDMO market dynamics continue to be favourable benefiting from increasing outsourcing trends and growth of molecules in clinical development, particularly in oncology where we can leverage our potent drug handling capabilities at Greenville. In the US, Metrics Contract Services supports more than 60 projects of which 16 products are in phase III and five are commercial products. These are typically first-in-man, high value and innovative developments – whereby Mayne Pharma is able to capture value across multiple phases of any project and we often retain this relationship and revenue opportunity across the full product lifecycle. In Australia, our Contract Services business has 25 programs under management of which 20 are commercial products. This year, we are making further capex investments of ~A\$15m into our two sites to further enhance capacity and support planned commercial manufacturing growth.

Finally, in terms of our cost base we are continuing to see material operating expense savings as I will highlight shortly in the trading update. We have a broad program to drive efficiencies across our entire supply chain through reducing product cost with new supply agreements such as the recent deal with Novast Laboratories where we secured supply on more favourable terms for eight products previously supplied by Teva. We continue to seek more economic sources of active drug raw materials, drive overhead recovery improvements in our manufacturing plants and distribution efficiencies through the way we ship our products via sea or air.

## YTD Trading

Moving to YTD trading. At a group level, revenue to the end of October was A\$140m, down 9% on the prior corresponding period (pcp). These results were impacted by the weakening USD FX rate which increased 3c to 0.715 and a softer generic result. Group gross profit margin has remained consistent year on year at 47% and operating expenses have fallen by 20% or A\$10m benefiting from the restructure undertaken in FY20 and continued cost containment. Pleasingly, at the underlying EBITDA line, the result was marginally above the prior corresponding period.

On a constant currency basis, YTD FY21 revenue and gross profit was consistent with the monthly average in the 2HFY20 highlighting the stability of the business since the beginning of this calendar year.

### *Specialty Brands Division (SBD)*

Specialty Brands Division revenue was US\$17m in the first four months of FY21 down 3% on pcp impacted by COVID and unfavourable changes to managed care coverage that occurred across FY20. Notwithstanding the significant restructure that occurred to the dermatology sales team in FY20, prescription volume performance has been consistent over the first four months versus pcp. SBD operating expenses have decreased by US\$4m versus the prior period driving a more profitable business.

The NEXTSTELLIS operating expense investment year to date has been US\$400,000 with significant further spending expected to be aligned to our confidence around the approvability of the dossier as we progress through future stage gates with the FDA.

### *Generic Products Division (GPD)*

Generics Products Division revenue was US\$55m in the first four months of FY21 down 10% on pcp. Performance of key products was mixed with growth in liothyronine, budesonide and carbidopa/levodopa offset by weaker performance in methylphenidate, amiodarone and butalbital.

GPD has seen limited benefit from new product launches so far this year but in the second half we look forward to the planned launch of five already approved products including four oral contraceptive products sourced from Novast and chlorpromazine tablets which participates in a US\$120m addressable market. In addition, the Company is expecting to yield more than US\$5m of cost savings from product transfers, stronger manufacturing overhead recovery and improved product cost benefits in the second half of FY21.



## ASX Announcement

### *Metrics Contract Services (Metrics or MCS)*

Metrics Contract Services reported revenue of US\$17m in the first four months of FY21, consistent with the pcp. Whilst the sales line reflects some delays in programs due to COVID-19, gross profit was up on pcp reflecting a better business mix. In terms of outlook, the pipeline of committed business revenue which reflects the next six months of signed statements of work was up more than 10% versus the balance at the end of FY20.

### *Mayne Pharma International (MPI)*

Mayne Pharma International sales were A\$15m in the first four months of FY21 up 11% on pcp benefiting from strong growth in third party contract development and manufacturing services and growth in select commercial products in Australia.

Finally, I would like to thank the executive leadership team and all our employees for their tireless commitment, agility and passion. I am confident that successful execution of our key priorities will deliver long-term sustainable growth.

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