24 November 2020

Manager, Company Announcements ASX Limited Level 4 20 Bridge Street SYDNEY NSW 2000

### Via E-Lodgement

Dear Sir/Madam

### **Mayne Pharma Group Limited**

Please find attached the presentation and addresses to shareholders to be delivered by the Chairman and the Chief Executive Officer at Mayne Pharma's Annual General Meeting today at 10.00am (Melbourne time).

The meeting will be webcast at <a href="https://web.lumiagm.com/?fromUrl=314771877">https://web.lumiagm.com/?fromUrl=314771877</a>.

For further information about the Annual General Meeting please refer to <a href="https://www.maynepharma.com/investor-relations/annual-general-meeting/">https://www.maynepharma.com/investor-relations/annual-general-meeting/</a>.

This announcement is authorised by the Chairman.

Yours faithfully, Mayne Pharma Group Limited

Laura @Koft

Laura Loftus
Company Secretary

### For further information, please contact

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### 2020 ANNUAL GENERAL MEETING

AT 10.00 AM ON 24 NOVEMBER, 2020

### CHAIRMAN'S ADDRESS

Good morning ladies and gentlemen, I'm Roger Corbett, the Chairman of our Company and I would like to welcome you all to the 2020 Mayne Pharma Annual General Meeting. As we have a quorum present, I am delighted to open the meeting.

First of all I would like to take you through the procedural aspects of the meeting today. Today's meeting is clearly different to prior years and is being held virtually for the first time. Shareholders and proxy holders have the ability to ask questions and submit votes. In the event we experience a technical difficulty and I cannot participate in the meeting, the Board has agreed that Ian Scholes, another Mayne Pharma director, will stand in.

Questions can be submitted at any time through the online platform and you do not need to wait for the relevant item of business to ask your questions. We encourage you to lodge questions now. If you experience any difficulties during the meeting please call the AGM help line on +61 3 9415 4024 which is listed in the AGM user guide on our website. We will address questions at the relevant time in the meeting and questions may be moderated or if we receive multiple questions on one topic they will be combined together. Finally, due to time constraints, it is possible that we may not be able to answer all questions. If that occurs, then we will revert back to you individually after the meeting about your unanswered question.

Voting today will be conducted by way of a poll on all items of business. Voting for all resolutions is now open and the poll will remain open during the AGM so that you can vote on all items at any time during the meeting. If you are eligible to vote at this meeting, a polling icon should be displayed on your screen. Click on this icon which will bring up a list of resolutions and present you with voting options. To cast your vote, select one of the available options. There is no 'Submit' or 'Enter' button as the vote is automatically recorded based on your selection. You have the ability to change your vote up until the time I declare the voting is closed at which time your most recent selection will be registered.

I would now like to introduce our Board members, senior executives, and the Company's auditor who are all online today. Joining me in Sydney are fellow Directors - Professor Bruce Robinson and Nancy Dolan. In Melbourne is Ian Scholes; Peter Paltoglou, our CFO and David Petersen, the Company's auditor. In the US, we have our CEO Scott Richards and two non executive directors - Frank Condella and Pat Blake. Bruce Mathieson is online from Queensland. We also have online Lisa Pendlebury, VP of Investor Relations



who will moderate the shareholder questions that have been asked both prior to this meeting and during the meeting and our Company Secretary, Laura Loftus.

I'll now outline the procedure for today's meeting. There are three items of business on today's agenda:

- 1. I will present my Chairman's Report, then
- 2. Scott will provide an update on the trading performance and our key strategic priorities, and then
- 3. We will go into the formal part of the meeting where we will vote on the resolutions outlined in the notice of meeting. We will then conclude the meeting.

### I will now move to the Chairman's Report.

First of all, I would like to express my disappointment in the performance of Mayne Pharma and in the share price which has fallen significantly over the last four years. Your Board and management team, who are significant shareholders in Mayne Pharma, are well aware of this and are committed and highly motivated to turnaround performance and restore shareholder value.

This time last year we anticipated some high value generic products would be approved by the FDA by the end of this calendar year. Unfortunately, this has not been the case and we have experienced delays from the FDA on two key generic products including a generic version of NUVARING<sup>®</sup>. We remain confident in bringing these products to the US market in a timely manner based on our ongoing dialogue with the FDA and our development partners.

As many of you would know, the US pharmaceutical market has experienced significant disruption over the last four years driven by the consolidation of wholesalers, retailers, insurers and pharmaceutical benefit managers driving heightened levels of price deflation, unfavourable changes to customer trading terms and reduced managed care coverage which has impacted both our generic and brand business.

This year we have also been faced by the COVID-19 pandemic which has created unprecedented challenges to our business. Our two key priorities during this pandemic have been to ensure the health and safety of our employees and maintain an uninterrupted supply of medicines and services to our customers and patients around the world. The greatest impact from COVID-19 was in our US brand business which faced a decline in prescribing driven by physician office closures or reduced capacity at these offices and less patient visits.

Notwithstanding these challenging market dynamics, your management team has been focused in FY20 on repositioning the business for growth through investing in



sustainable products, distribution channels and therapeutic areas, restructuring our cost base and rationalising the generic portfolio.

As indicated at the AGM last year, the licensing of the novel oral contraceptive NEXTSTELLIS® (E4/DRSP) in the US and Australia is highly consistent with our strategy to build our business with durable high growth products in core therapeutic categories leveraging our commercial infrastructure.

We have worked extensively on optimising our cost base. Over FY20 we decreased operating expenses by A\$16m versus the prior corresponding period (pcp). A significant part of these savings have been in our dermatology business, where we have restructured our sales team to drive a more profitable operating model inline with market changes. In addition, gross research and development spend decreased by A\$15m.

Whilst we have continued to invest in R&D and business development activities, we have refocused from the more volatile retail generic segment to more sustainable areas in women's health, dermatology and infectious disease.

Moving to the actual FY20 results.

The Company reported revenue of A\$457m, down 13% on pcp, reported EBITDA of A\$80m and underlying EBITDA of A\$95m. At the bottom line, the Company reported a net loss after tax which was largely impacted by intangible asset impairments of the generic portfolio. In terms of cashflow we delivered a solid result generating A\$100m of operating cashflow and were able to reduce our net debt by A\$32m to A\$248m<sup>1</sup>.

In terms of our segments, Metrics Contract Services delivered another good result with revenue up double digits benefiting from favourable market dynamics and new development and commercial manufacturing revenues. Generic Products was impacted in FY20 by competition on its key products and abnormal gross-to-net charges and inventory adjustments on discontinued products. Specialty Brands was impacted by COVID-19, as well as new competition in the acne and psoriasis space and the tougher managed care environment. Finally, Mayne Pharma International, our rest of world business, grew revenue benefiting from new contract services and manufacturing revenues along with growth in key specialty products – UROREC® (silodosin) and MONUROL® (fosfomycin).

Now I would like to make some comments about the future and the key initiatives to return Mayne Pharma to sustainable growth.

Firstly, the successful commercialisation of NEXTSTELLIS is expected to be transformational for Mayne Pharma. NEXTSTELLIS will compete in the short-acting

<sup>&</sup>lt;sup>1</sup> Excludes lease liabilities



combined hormonal contraceptive market which is valued at US\$4b in the US and A\$70m in Australia. Our business plan for NEXTSTELLIS is targeting peak net sales of US\$200m in the US which represents approximately 2% of the market by units. In April this year we filed NEXTSTELLIS with the FDA and have a Target Action Date in April 2021. In Australia, we filed NEXTSTELLIS with the TGA in August.

Secondly, we are also focused on expanding our dermatology and women's health portfolios through R&D and selective business development activities. In women's health, we have a number of pipeline products including some high value complex programs such as the generic version of NUVARING. The generic NUVARING program remains highly attractive, with only one independent generic approved and an addressable market of US\$900m². In dermatology, we launched three new generic products in FY20 following partnerships with Teligent and Encube, topical developers and manufacturers. We continue to have active discussions with a number of parties around further product collaborations in dermatology to build on our differentiated business model.

We continue to invest in our SUBA®-itraconazole platform and have recently announced results from an endemic clinical study which investigated TOLSURA® (SUBA-itraconazole) versus conventional itraconazole in the treatment of endemic fungal infections. This data demonstrated some of the clinical advantages of TOLSURA, including that the product was safe, well-tolerated and consistently leads to itraconazole levels that are higher than conventional itraconazole but administrated at substantially lower doses. We continue to believe in the potential of this product to capture a meaningful share of the US itraconazole market over time.

Globally, we have two contract development and manufacturing organisations (CDMO) supporting more than 100 active clients including 14 of the top 20 global pharma companies. Our technical expertise and capability is centered on complex oral and topical dosage forms with a focus on potent compounds such as oncology medications. The US business, Metrics Contract Services, has demonstrated a solid track record of double digit growth benefiting from the investments we made in the Greenville site including the US\$80m solid oral dose manufacturing facility that was completed in 2018. In Australia, the business trades under Mayne Contract Services and leverages Salisbury's 40 years of history in developing new oral drug delivery systems which have been successfully commercialised in numerous products that are marketed around the world.

Finally, the Company continues to improve its cost base through greater operating efficiencies in our manufacturing network and cost savings through the realignment of our supply chain. In Greenville, our manufacturing dose volumes were up 57% in FY20 versus pcp. We continue to look at ways to increase our volumes in both our plants and

<sup>&</sup>lt;sup>2</sup> IQVIA MAT Sales, September 2020



we hope to be able to leverage over time government policies to increase the domestic manufacture of critical medications.

I would now like to make a few comments on Board renewal following the announcement we made a few weeks back. A core part of any business is to ensure succession planning and renewal. It is my intention to retire from the Mayne Pharma Board within the next 12 months, along with my fellow director Mr Bruce Mathieson. At the time of my retirement we will appoint a US-based Chairman considering more than 90% of our revenues are in that market and we will also appoint a Deputy Chairman based in Australia. As part of this renewal process we plan to seek further diversity, skills and experience in the US pharmaceutical sector.

Finally, I would like to thank all the employees and our leadership team for their hard work and commitment and most importantly all our shareholders for your patience, loyalty and support. 2020 has been an unprecedented year with the global pandemic and we look forward to the impact the pharmaceutical industry will have in 2021 to bring normality back to society.

With that, I will now hand over to Scott.

### 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 antifungal 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.



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<sup>®</sup>, 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.

# mayne pharma

# **ASX Announcement**

We continue to remain confident about the potential of TOLSURA® (SUBA®-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.

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# **ASX Announcement**

### 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.



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)

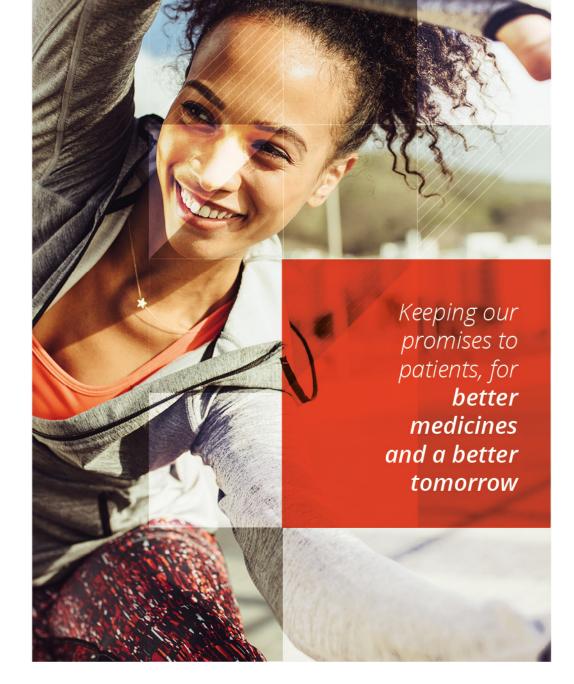
Mayne Pharma International sales were A\$15m in the first four months of FY21 up 11% on pcp benefiting from strong growth in third party contract development and manufacturing services and growth in select commercial products in Australia.

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.

# Mayne Pharma Group Limited

Annual General Meeting 10.00am (Melbourne time) 24 November 2020







### Disclaimer

The information provided is general in nature and is in summary form only. It is not complete and should be read in conjunction with the company's audited Financial Statements and market disclosures. This material is not intended to be relied upon as advice to investors or potential investors.

### Non-IFRS information

- Other than as indicated, the financial information contained in this document is directly extracted or calculated from the audited Financial Statements. Throughout this document some non-IFRS financial information is stated, excluding certain specified income and expenses. Results excluding such items are considered by the Directors to provide a meaningful basis for comparison from period to period.
- Earnings before interest, tax, depreciation and amortisation (EBITDA) a non-IFRS term is considered by Directors to be a meaningful measure of the operating earnings and performance of the Group and this information may be useful for investors.
- The non-IFRS financial information has not been audited by the Group's auditors.

### **Forward looking statements**

• This presentation contains forward-looking statements that involve subjective judgement and analysis and are subject to significant uncertainties, risks and contingencies, many of which are outside the control of, and are unknown to the Company. These forward looking statements use words such as 'potential', 'expect', 'anticipate', 'intend', 'plan' and 'may', and other words of similar meaning. No representation, warranty or assurance (express or implied) is given or made in relation to any forward looking statement by any person (including the Company). Actual future events may vary materially from the forward looking statements and the assumptions on which the forward looking statements are based. Given these uncertainties, readers are cautioned not to place undue reliance on such forward looking statements. Subject to the Company's continuous disclosure obligations at law and under the listing rules of the Australian Securities Exchange, the Company disclaims any obligation to update or revise any forward looking statements. The factors that may affect the Company's future performance include, among others: changes in economic conditions, changes in the legal and regulatory regimes in which the Company operates, litigation or government investigations, decisions by regulatory authorities, changes in behaviour of major customers, suppliers and competitors, interruptions to manufacturing or distribution, the success of research and development activities and research collaborations and the Company's ability to protect its intellectual property.

#### Other

- A glossary of industry terminology is contained in the Mayne Pharma Annual Report which can be accessed at <u>maynepharma.com/investor-relations/results-reports</u> and product descriptions are detailed at <u>maynepharma.com/us-products</u> and <u>maynepharma.com/australian-products</u>.
- NEXTSTELLIS™ and NUVARING® are registered trademarks of third parties.



# Introduction

### **Non-executive Directors**

Chairman

**Roger Corbett** 

CEO & Managing Director

CFO



**Scott Richards** 



**Peter Paltoglou** 



**Pat Blake** 



**Frank Condella** 



**Nancy Dolan** 



**Bruce Mathieson** 



**Prof Bruce Robinson** 



Ian Scholes



# **Agenda**

- 1. Chairman's Address
- 2. CEO & Managing Director's Address
- 3. Formal Business
- 4. Closing



# **CHAIRMAN'S ADDRESS**

MR ROGER CORBETT

# mayne pharma

### FY20 overview

- Reported revenue of A\$457m, down 13%
- Reported EBITDA of A\$80m and underlying EBITDA of A\$95m
- Reported net loss after tax of A\$(93)m driven by asset impairments
- Positive operating cash flow of A\$100m with cash conversion exceeding underlying EBITDA
- Net debt reduced by A\$32m to A\$248m<sup>1</sup> with bank leverage ratio 2.5x
- Licensed novel oral contraceptive NEXTSTELLIS™ (E4/DRSP) in the US and Australia and submitted NDA with the FDA
- Restructured Specialty Brands right sizing dermatology cost base
- Generic Products impacted by competition on key products
- Metrics Contract Services delivered solid revenue growth with sales up 15%



# Our key priorities to return Mayne Pharma to sustainable growth



Commercialisation of novel oral contraceptive NEXTSTELLIS® (E4/DRSP)



Expand
dermatology and
women's health
portfolios and
advance key
pipeline products



Maximise SUBA®itraconazole franchise



Accelerate contract services platform globally



Optimisation of cost base



# **CEO and MANAGING DIRECTOR'S ADDRESS**

MR SCOTT RICHARDS



# Key priorities and anticipated milestones

Commercialisation of novel oral contraceptive NEXTSTELLIS™

Expand dermatology and women's health portfolio and advance key pipeline products

- Maximise SUBA® itraconazole franchise
- Accelerate contract services platform globally

**Optimisation of cost base** 

- FDA approval and successful launch of NEXTSTELLIS™ in the US
- Recruit new women's health team in the US
- TGA filing of NEXTSTELLIS™ in Australia
- Successful launch of products pending at FDA (eg. gNUVARING®)
- Launch up to five additional women's health OCs sourced from Novast
- Continue to expand portfolio through business development activities
- Complete enrolment for phase II trial with trifarotene in lamellar ichthyosis patients
- Accelerate TOLSURA® sales
- Broaden potential for therapeutic use through further clinical programs
- Invest in new capabilities and people to accelerate growth (ie. Expansion of production space in Greenville and addition of new equipment)
- Expansion of commercial manufacturing client base in Greenville and contract development client base in Salisbury
- Improve cost base of contraceptive portfolio through new supply agreements
- Improve overhead recovery benefits in manufacturing plants
- Continued management of R&D and SG&A expenses



# Year to date trading update (Jul-Oct 20)

- Reported revenue A\$140m, down 9% on prior corresponding period (pcp) impacted by weaker USD and softer generic result
  - On a constant currency basis, YTD FY21 revenue was consistent with the monthly average in the 2HFY20
- Gross profit margin consistent with pcp at 47%
- GPD revenue US\$55m down 10% on pcp
- SBD revenue US\$17m down 3% on pcp
- MCS revenue US\$17m flat on pcp
- MPI revenue A\$15m up 11% on pcp
- Operating expenses down ~20% on pcp
- Underlying EBITDA marginally ahead of pcp