

21 November 2024

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 AGM presentation which contains a business update to be delivered to shareholders at Mayne Pharma's Annual General Meeting today at 1:00pm (Melbourne time) at Minter Ellison, Level 20, Collins Arch, 447 Collins St, Melbourne VIC 3000.

The meeting will be webcast at <https://meetnow.global/MZQQXKD>.

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

This announcement is authorised by the Board.

Yours faithfully,  
Mayne Pharma Group Limited



Laura Loftus  
Company Secretary

**For further information contact:**

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Improving patient access to  
**life-enhancing** medications

# Mayne Pharma Group Limited

Annual General Meeting  
1.00pm (Melbourne Time)

21 November 2024



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.

## 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 [maynepharma.com/investor-relations/results-reports](https://www.maynepharma.com/investor-relations/results-reports) and product descriptions are detailed at [maynepharma.com/us-products](https://www.maynepharma.com/us-products) and [maynepharma.com/au-products](https://www.maynepharma.com/au-products).
- DORYX®, FABIOR®, KAPANOL®, LEXETTE®, RHOFADÉ® and SORILUX® are trademarks of Mayne Pharma. ACCUTANE®, ANNOVERA®, BIJUVA®, IMVEXXY®, KADIAN®, NEXTSTELLIS®, ORACEA®, SOOLANTRA®, UROREC® and WYNZORA® are trademarks of third parties.

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# Chair

Frank Condella

A decorative graphic in the bottom right corner consisting of several overlapping triangles in various shades of red, creating a geometric pattern.

## Introduction – Directors and KMP



David Petrie  
**Non-Executive Director**



Prof Bruce Robinson  
**Non-Executive Director**



Anne Lockwood  
**Non-Executive Director**



Shawn Patrick O'Brien  
**CEO & Managing Director**



Dr Katie Macfarlane  
**Non-Executive Director**



Ann Custin  
**Non-Executive Director**



Patrick Blake  
**Non-Executive Director**



Frank Condella  
**Chair**



Aaron Gray  
**CFO**

## Agenda

**1**

**Chair's Address**

**2**

**CEO Business Update**

**3**

**Formal Business**

**4**

**Close**

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# Chair's Address

Frank Condella

A decorative graphic in the bottom right corner consisting of several overlapping triangles in various shades of red, creating a geometric pattern.



# **Business Update**

Shawn Patrick O'Brien



- FY24 Recap
- FY25 Business Update
  - Women's Health
  - Dermatology
  - International
- Outlook

## Mayne Pharma Transformation FY22-FY24

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### FROM

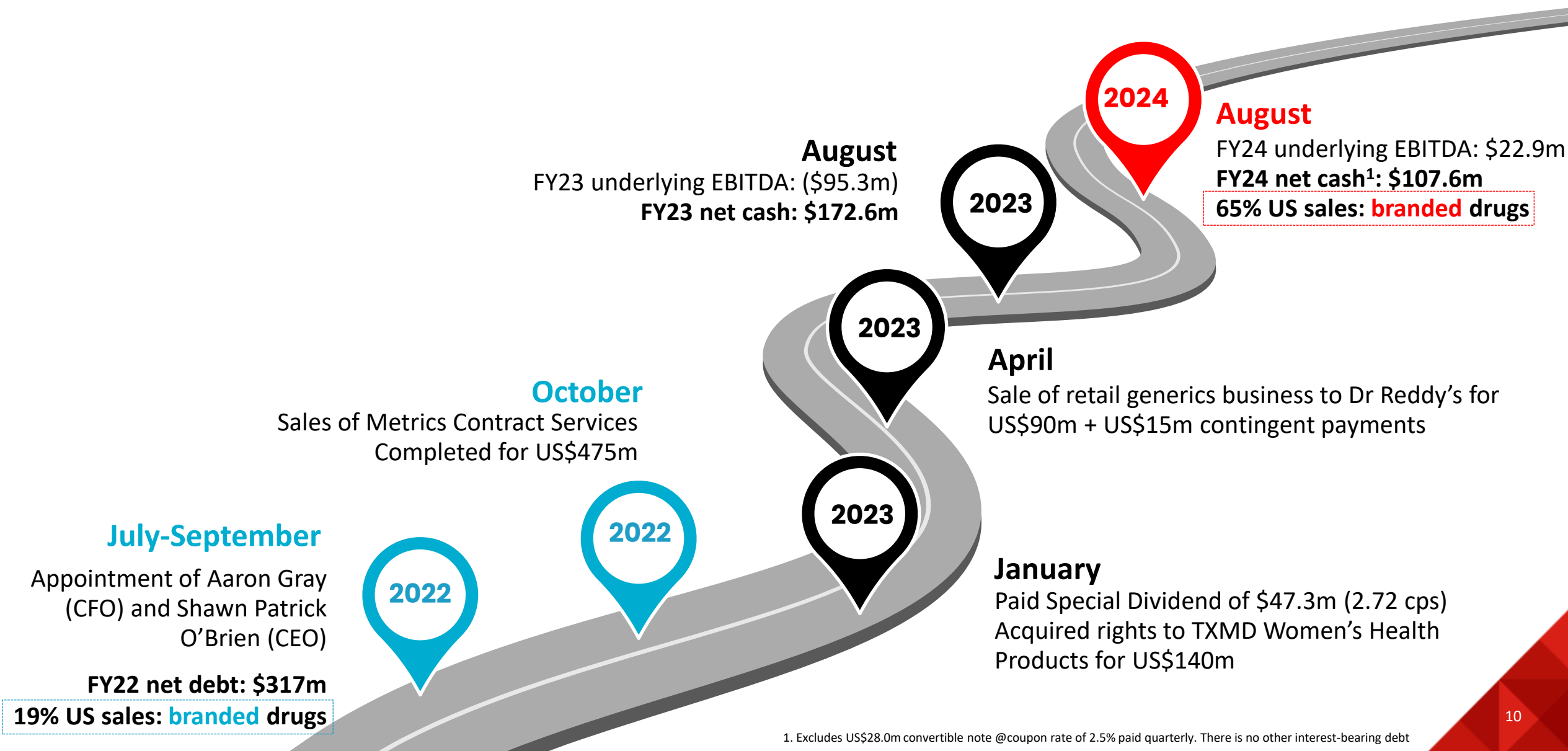
- Large debt and debt service obligations
- Significant discontinued operations
- Large amounts of cash tied up in Net Working Capital (NWC)
- Positioned in markets that were stable / declining (contract development, retail generics)
- Core products driving revenues had little / no channel strategy or IP protection

A red location pin icon with a white circle in the center containing the word "TO" in bold black uppercase letters.

### TO

- Strong net cash position
- Discontinued and restructuring adjustments reduced to \$7.2m (from \$33.7m)
- NWC as a % revenue profile has declined markedly
- Company has generated positive cash from operations 3 of last 4 quarters (ex. class action settlement)
- Positioned in growing markets with a channel strategy and IP that provides significant protection to revenues

# Mayne Pharma Transformation FY22-FY24



1. Excludes US\$28.0m convertible note @coupon rate of 2.5% paid quarterly. There is no other interest-bearing debt

## FY24 Operating Highlights

### Women's Health



- 3 new US FDA Orange-Book listed NEXTSTELLIS® patents expiring 2036
- NEXTSTELLIS® achieved breakeven run rate from December and delivered positive contribution in 2HFY24
- 85% growth in demand cycles<sup>1</sup> for NEXTSTELLIS®, compared to FY23
- 31% growth in demand TRx<sup>2</sup> from licensed portfolio: ANNOVERA®, IMVEXXY® and BIJUVA®

### Dermatology



- Completed asset purchase agreement to acquire the global rights to RHOFADÉ® from Novan, Inc. and EPI Health, LLC.
- New product launches driving growth – RHOFADÉ®, WYNZORA®, SOOLANTRA®, gACCUTANE® and authorised generic (AG) ORACEA®
- Channel strategy validated, moving to scale
- Shift towards products with more favourable gross to net profile

### International



- Growth of NEXTSTELLIS®, oxycodone and UROREC® in Australia
- Modernisation project progressing well: new encapsulator in commercial production, enabling launch of KAPANOL® 200mg in FY24
- Increased demand for KADIAN® /KAPANOL® in Canada and Europe and expansion with business partners in other overseas territories
- Salisbury facility demonstrated significant positive step change in key operational metrics in a sustainable manner

1. Demand cycles calculated as IQVIA reported TRx (converted to units/cycles) plus non-reporting pharmacies (including Mayne Pharma's own distribution channel). TRx converted to units by taking number of pills in the TRx divided by 28 (number of NEXTSTELLIS® pills included in 1 month of therapy).

2. TRx – total prescriptions. For the period up to 31 December 2022 (prior to Mayne Pharma's purchase of license from TXMD), the data captures unadjusted IQVIA data only. For the period from 1 January 2023 (when Mayne Pharma started selling the products), the data includes IQVIA data, plus prescription volume through non-reporting pharmacies (including Mayne Pharma's own distribution channel).

## FY24: Strong financial results by delivering on all goals<sup>1</sup>

*Simplification of our business model combined with our strong operating and financial discipline has delivered significantly improved financial results*

**\$388m**

Revenue  
up 112% FY23

**56.3%**

Gross margin  
up from 45.5% FY23

**\$22.9m**

Underlying EBITDA<sup>2</sup>  
up from (\$95.3m) FY23

**\$88.5m**

Segment contribution  
up from (\$41.8m) FY23

**\$8.1m**

Operating cashflow from  
continuing operations<sup>3</sup>  
up from (\$51.5m) FY23

**\$149.3m**

Cash and marketable  
securities at 30 June 2024  
down from \$220.1m FY23

1. All numbers are expressed in AUD/A\$ terms unless otherwise stated.

2. Underlying EBITDA is a non-IFRS measure and excludes earn-out reassessments, restructuring charges, class action settlement costs, derivative fair value adjustments and litigation expense.

3. Total net operating cashflow (continued + discontinued operations) for FY24 was an outflow of \$15.3m, a reduction of 64% compared with FY23.



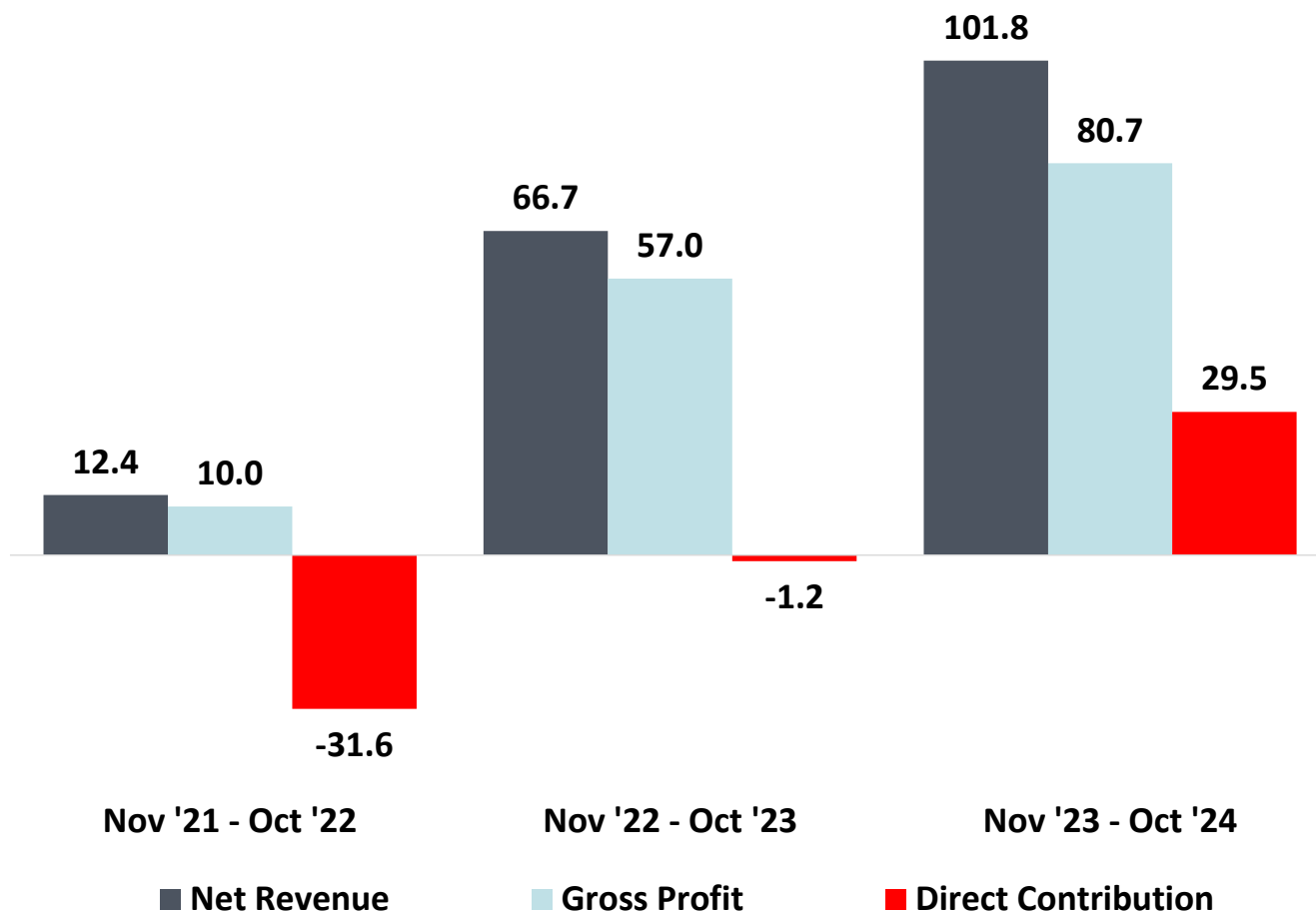
### Women's Health

#### **Deliver profit potential of current Women's Health asset portfolio**

- Drive growth through sharpened focus on sales execution and targeted marketing
- Continue to raise product scientific awareness
- Further operating leverage to accelerate EBITDA growth



## Women's Health (US\$m)



### Commentary

- US\$140m investment capital deployed driving US\$61m improvement in annual contribution with significant headroom for growth going forward
- Improved cost leverage (direct opex divided by revenue) for the US business from 336% to 50% in the past two years

1. All numbers shown in USD.

2. Direct contribution calculated as gross margin less direct opex.

3. Women's Health figures above do not include royalties to Population Council or TXMD for ANNOVERA®, IMVEXXY® and BIJUVA®. See Appendix for royalty terms.

# Business Update – Women’s Health

(4 months to 31 October 2024)

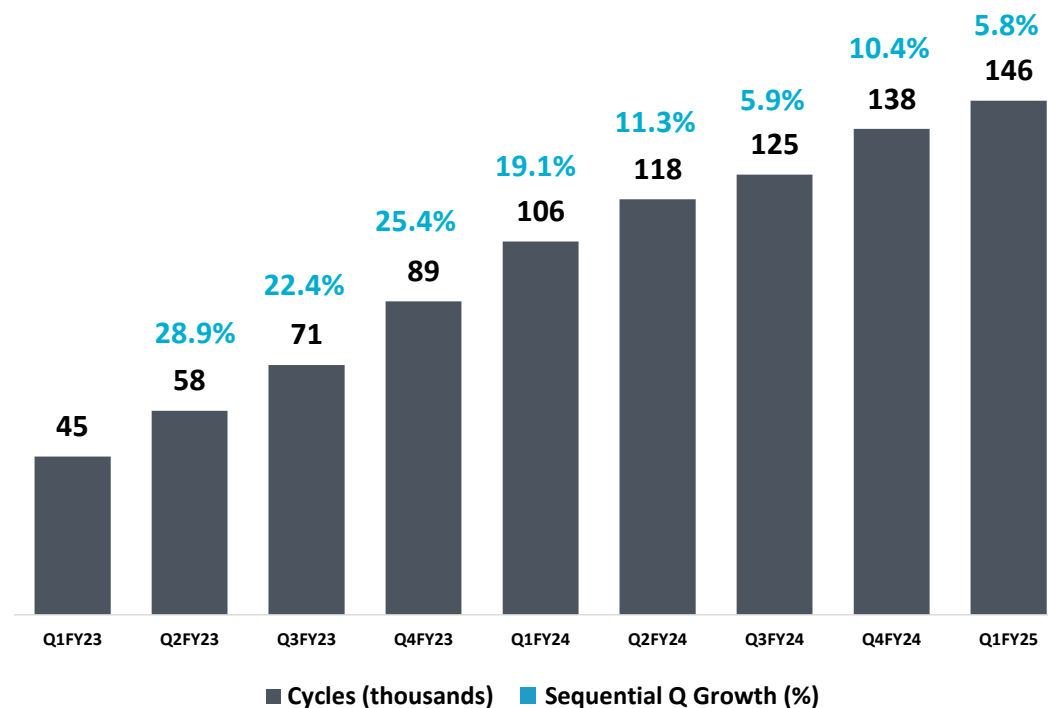
## Women’s Health



- Strong revenue and direct contribution growth recorded, improvement in gross to net sales across the portfolio
- Record month of demand cycles in October for NEXTSTELLIS® (51.5k) – up 33% on pcp and 10% on September
- Change of US government unlikely to impact positive momentum observed relating to increasing women’s access to contraception (NEXTSTELLIS®, ANNOVERA®) and menopause (BIJUVA®, IMVEXXY®) treatments
- Net Selling Price (NSP) holding steady with continued volume growth



## NEXTSTELLIS® Quarterly US Demand Cycles (thousands)







## FY25 Performance (Jul-Oct) – Women’s Health

*28% growth versus the prior comparable 4-month period (pcp)*



US\$m

	Jul-Oct FY24 (pcp)	Mar-Jun FY24 (seq.)	Jul-Oct FY25	Change (vs. pcp)	Change (vs. seq.)
<b>Womens' Health</b>					
<b>Total Revenue</b>	<b>30.6</b>	<b>30.5</b>	<b>39.3</b>	<b>28%</b>	<b>29%</b>
<i>Total Gross Profit % of Revenue</i>	82%	77%	82%		
<b>Direct Contribution*</b>	<b>5.4</b>	<b>7.5</b>	<b>16.4</b>	<b>203%</b>	<b>117%</b>

## Strategic factors to drive NEXTSTELLIS® long term revenue



### 1. Drive improved market access

- A. Affordable Care Act (ACA)
- B. Reduction in prior authorisation (if no ACA)

### 2. Improve HCP / patient knowledge and confidence in the superiority of the brand

### 3. Recapture milestone payments and COGs markup at a value-accretive discount to NPV

### 4. Enhance IP through additional patent protection

## Strategic factors to drive ANNOVERA® long term revenue



### 1. Improve supply

- A. Ramp up production to multiples of current run rates
- B. Production improvements to improve COGs

### 2. Label improvement (working with Population Council)

- A. Continuous use up to 12 months versus current monthly label
- B. Continued education of the market and wholesale distributors around expiration dates for ANNOVERA®

### 3. Shelf life expanded to 24 months (approved Nov 2024)

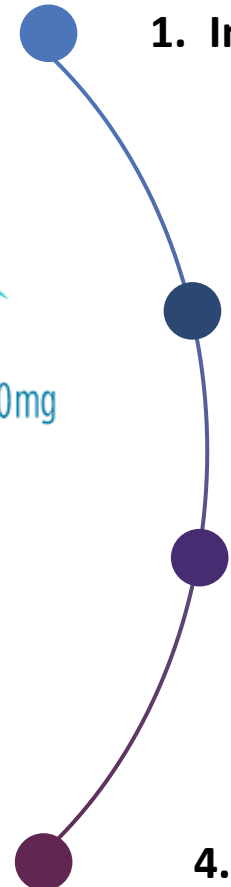
- A. Improves ability to build safety stock, reduces returns risk

### 4. Improved market access

- A. Affordable Care Act (ACA)

## Strategic factors to drive BIJUVA® long term revenue



- 
- A curved line with four circular nodes connects the four strategic factors. The nodes are colored in a gradient from light blue at the top to dark purple at the bottom.
1. Improved dosing strategy (packaging 0.5mg)
  2. Drive HCP and patient awareness on hormonal benefits and best in class profile
  3. Catch the social inertia around effective menopause treatments
  4. Co-pay optimisation (resetting caps)



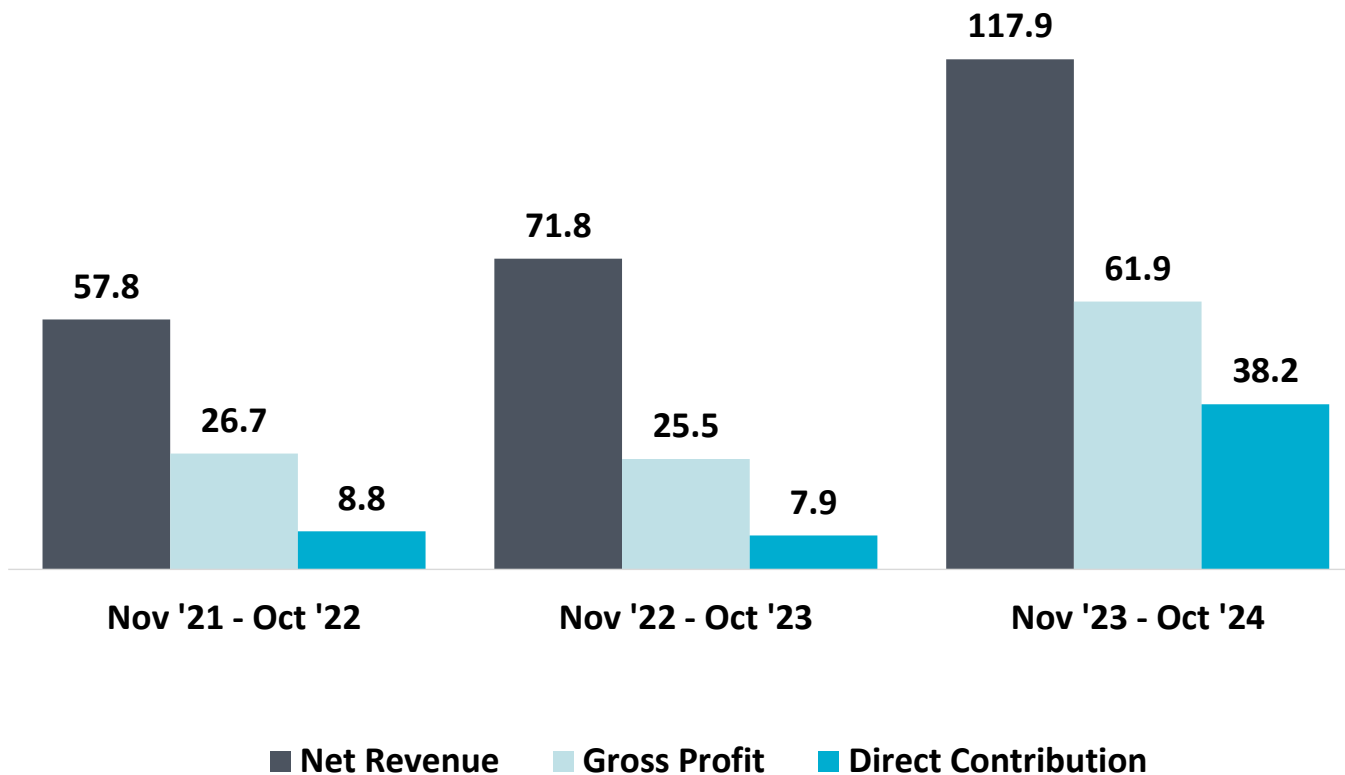
### Dermatology

**Differentiate channel strategy to enable preferred solution for patients, prescribers and partners**

- Continue to evaluate capital efficient and accretive business arrangements to further drive growth in revenue and margin
- Ensure channel strategy processes are easy to use
- Continuous development of channel strategy, leveraging ability to drive market share, access and financial performance



## Dermatology (US\$m)



### Commentary

- US\$8m investment capital deployed driving US\$29m improvement in annual contribution with significant headroom for growth going forward
- Improved cost leverage (direct opex divided by revenue) for the US business from 31% to 20% in the past two years

1. All numbers shown in USD.

2. Direct contribution calculated as gross margin less direct opex.

# Business Update - Dermatology

(4 months to 31 October 2024)



## Dermatology

- Channel strategy (disintermediation) showing strong growth – annualised sales run rate tracking 2x higher versus FY24
- RHOFADE<sup>®</sup> NRx growth of 151% versus pcp<sup>1</sup>
- Realised market share<sup>2</sup> of ~54% with stable pricing for AG ORACEA<sup>®</sup>, despite new generic launches
- New product launches planned (no launches in Q4 FY24 and FY25 YTD)
- FY25 YTD sales impacted by seasonality associated with acne and rosacea products

1. Mayne Pharma acquired RHOFADE<sup>®</sup> in September 2023 and re-launched October 2023. Growth calculation based on IQVIA data (July-Oct 2023) and Mayne Pharma data (Oct 2023) vs. IQVIA data (July 2024 – Oct 2024)

2. Market share calculated based on therapeutic equivalents of ORACEA<sup>®</sup> (branded ORACEA<sup>®</sup>, AG ORACEA<sup>®</sup>, generic competitors and Doxycycline IR 40mg capsule)

AG – Authorised generic

## FY25 Performance (Jul-Oct) – Dermatology



US\$m

	Jul-Oct FY24 (pcp)	Mar-Jun FY24 (seq.)	Jul-Oct FY25	Change (vs. pcp)	Change (vs. seq.)
<b>Dermatology</b>					
<b>Total Revenue</b>	<b>35.9</b>	<b>42.8</b>	<b>33.0</b>	<b>-8%</b>	<b>-23%</b>
<i>Total Gross Profit % of Revenue</i>	<i>43%</i>	<i>51%</i>	<i>51%</i>		
<b>Direct Contribution*</b>	<b>8.5</b>	<b>11.8</b>	<b>7.5</b>	<b>-12%</b>	<b>-37%</b>





### International

**Drive International profit via new revenue streams and continuation of modernisation**

- Leverage capacity created by operational improvements to grow and further operating leverage
- Complete modernisation upgrade program (MMI) at the Salisbury facility to improve productivity and capabilities
- Continue to drive specialty and generic product sales, including driving growth in NEXTSTELLIS® in Australia

# Business Update - International

(4 months to 31 October 2024)



## International

- Modernisation activities (MMI project) continue to progress in-line with expectations
- New equipment delivery and validation ongoing
- Operational transformation trending positive with DIFOT<sup>1</sup> rate from Salisbury facility operating at 93.3% versus 32% as at October 2022

## FY25 Performance (Jul-Oct) – International

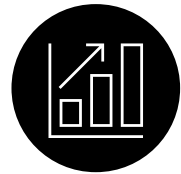


A\$m

	Jul-Oct FY24 (pcp)	Mar-Jun FY24 (seq.)	Jul-Oct FY25	Change (vs. pcp)	Change (vs. seq.)
<b>International</b>					
<b>Total Revenue</b>	<b>21.3</b>	<b>25.2</b>	<b>24.8</b>	<b>16%</b>	<b>-2%</b>
<i>Total Gross Profit % of Revenue</i>	37%	35%	34%		
<b>Direct Contribution*</b>	<b>4.0</b>	<b>4.3</b>	<b>4.1</b>	<b>3%</b>	<b>-5%</b>

## Business Update – Financials

### FY25 Jul-Oct



	Jul-Oct FY24 (pcp)	Mar-Jun FY24 (seq.)	Jul-Oct FY25	Change (vs. pcp)	Change (vs. seq.)
<b>Total (A\$m)</b>					
<b>Revenue</b>	<b>124.8</b>	<b>137.0</b>	<b>132.5</b>	<b>6%</b>	<b>-3%</b>
<i>Gross Profit % of Revenue</i>	<i>57%</i>	<i>57%</i>	<i>61%</i>		
<b>Direct Contribution*</b>	<b>26.4</b>	<b>33.9</b>	<b>39.6</b>	<b>50%</b>	<b>17%</b>

- Underlying EBITDA<sup>1</sup> of **\$14.7m** versus \$1.7m in the pcp, representing a \$19.6m improvement (**765% increase**) and a 34% increase from Mar-June 2024 (\$11.0m)
  - FY24 underlying EBITDA: \$22.9m
- Underlying free cash flow<sup>2</sup> of positive **\$16.1m**
  - One-off payment of \$33.3m (class action settlement), \$2.6m discontinued ops
  - Operating cash flow of **-\$6.3m**
- Cash and marketable securities of **\$129.5m** at 31 Oct versus \$149.3m (30 June)

1. Underlying EBITDA is a non-IFRS measure and excludes earn-out reassessments, restructuring charges, class action settlement costs, derivative fair value adjustments and litigation expense.

2. Underlying free cash flow is a non-IFRS measure and excludes shareholder class action settlement costs, certain litigation expense and restructuring charges and other one-offs

\*Direct contribution calculated as gross margin less direct opex.

All YTD FY25 results unaudited.

- The Company expects growth in underlying EBITDA and free cash flow in FY25 via revenue growth and cost leverage, with all three segments contributing positive direct contribution. Specifically, Mayne Pharma anticipates:
  - Women's Health growth continuing, Dermatology new product launch contribution, continued growth in MYX channel (disintermediation), international KAPANOL<sup>®</sup> export growth
  - Continued focus on operating expenditures to drive operating leverage and positive underlying free cash flow<sup>1</sup> generation
  - Underlying EBITDA<sup>2</sup> to show a significant improvement on pcp and further growth on the four months to 31 October 2024

1. Underlying free cash flow is a non-IFRS measure and excludes shareholder class action settlement costs, certain litigation expense and restructuring charges and other one-offs

2. Underlying EBITDA is a non-IFRS measure and excludes earn-out reassessments, restructuring charges, class action settlement costs, derivative fair value adjustments and litigation expense

# Contacts

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You deserve tomorrow.

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# Appendix



# Earn-Out and Deferred Consideration Liabilities - Update

	Royalties	Milestones
<b>Women's Health</b> 	8% Net Sales on all TXMD Licensed Products (ANNOVERA®, IMVEXXY®, BIJUVA®)	Population Council: US\$13.0m (2025) Population Council: US\$40.0m (cumulative sales of US\$400m: ANNOVERA®) Population Council: US\$40.0m (cumulative sales of US\$1.0bn: ANNOVERA®)
	10% Net Sales to Population Council (ANNOVERA®) <sup>1</sup>	TXMD: US\$100m in net revenue (US\$5m milestone payment) TXMD: US\$200m in net revenue (US\$10m milestone payment) TXMD: US\$300m in net revenue (US\$15m milestone payment)
	Variable COGS payment to Gedeon Richter (GR) (formally Mithra) (NEXTSTELLIS®) (Embedded in gross margin)	Dependent on forward sales of NEXTSTELLIS® (no guidance provided)
<b>Dermatology</b> 	N/M <sup>2</sup>	N/M
<b>International</b> 	N/M	N/M

Contingent consideration represents the estimated present value of the future royalties and milestones payable on net sales of the product

Carrying Value	FY24	FY23
Current	\$33.2m	\$15.2m
Non-Current	\$329.6m	\$252.1m

1. The 10% royalty is deducted from Net Sales of ANNOVERA® prior to the application of the 8% royalty payable to TXMD;

2. N/M – not material



# Orange Book Listed Patents – Major Branded

## Last Patent Expiry Women's Health

**2032**   
Bijuva® 1mg/100mg  
(estradiol and progesterone) capsules

**2034\***   
Imvexxy®  
(estradiol vaginal inserts)  
4 mcg • 10 mcg

**2036**   
nextstellis®  
(estetrol/drospirenone)

**2039**   
Annovera®  
(segesterone acetate and  
ethinyl estradiol vaginal system)  
Delivers 0.15 mg/0.013 mg per day

Average of 10.9  
years<sup>1</sup> of patent life  
remaining across key  
branded products

## Last Patent Expiry Dermatology

**2030**   
FABIOR®  
(tazarotene) Foam, 0.1%

**2034**   
Doryx® MPC  
(Doxycycline Hyclate  
Delayed-Release Tablets)

**2035\***   
Rhofade®  
(oxymetazoline HCl)  
cream, 1%

**2039**   
Wynzora®  
(calcipotriene and betamethasone dipropionate)  
Cream, 0.005%/0.064%

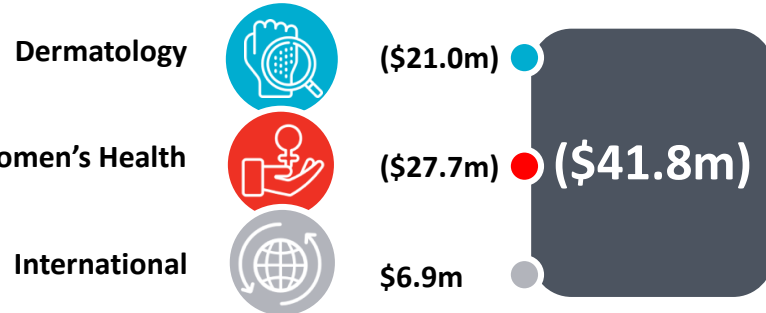
1. Average of last patent expiry from 2024 onwards. Source: Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations.

\* Paragraph IV challenges for IMVEXXY® brought by Sun Pharma and Teva. Potential RHOFADÉ® generic from 2026 (pending approval).

# Material Improvement in FY24 Direct Contribution<sup>1</sup>

Benefit of scale and leverage starting to be demonstrated

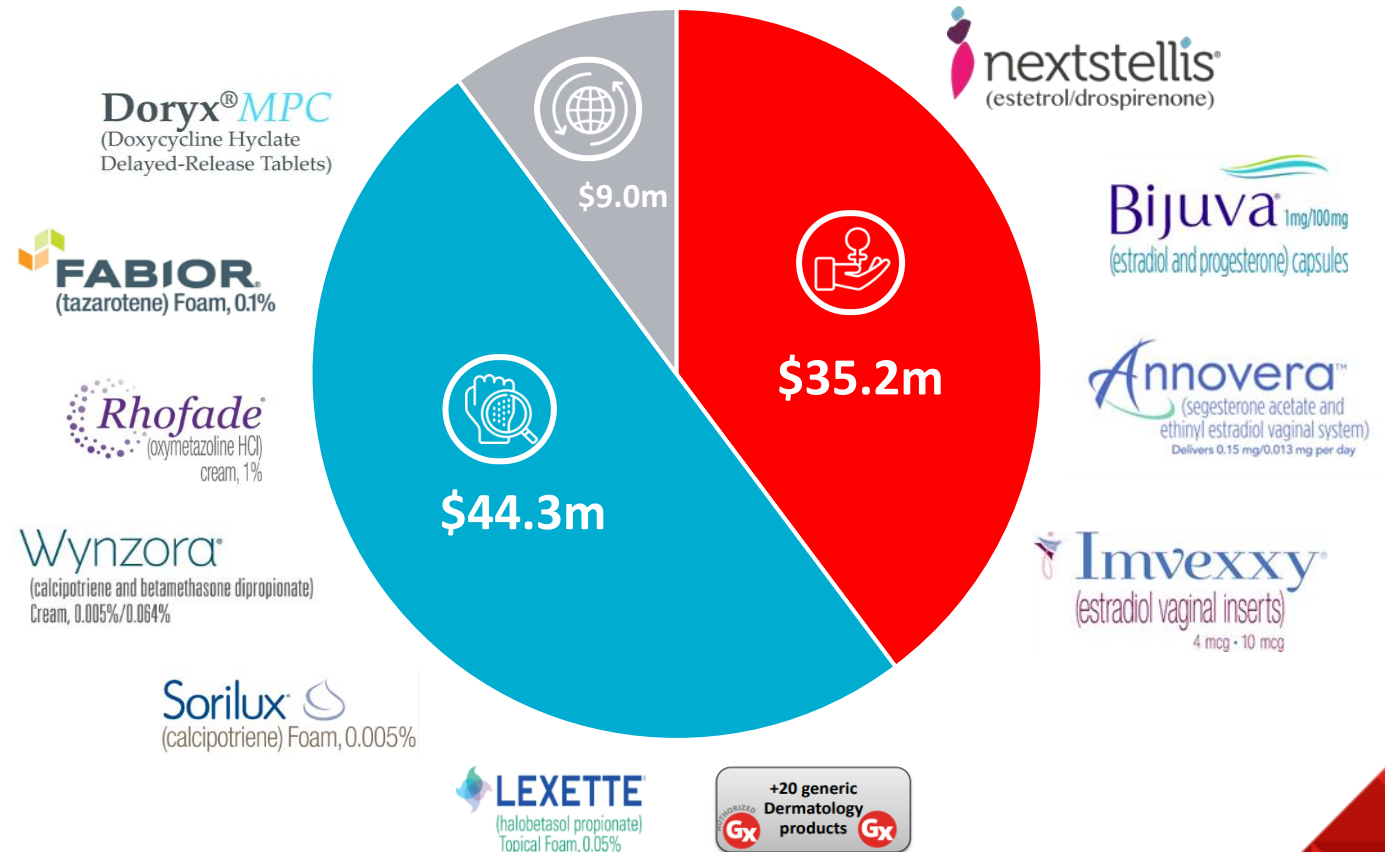
## FY23 Total Direct Contribution



**+\$130.3m**

## FY24 Total Direct Contribution

**\$88.5m**



1. Direct contribution calculated as gross margin less direct opex.