

23 February 2026

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

**Via E-Lodgement**

Dear Sir/Madam

**Mayne Pharma Group Limited  
Interim Results**

Please find attached the Appendix 4D Half Year Report, Directors' Report, the Financial Report and Auditor's Independent Review Report relating to the results for the half-year ended 31 December 2025.

This information should be read in conjunction with Mayne Pharma Group Limited's 2025 Annual Report.

This announcement comprises the information required by ASX Listing Rule 4.2A and the statement required by Rule 4.2C.2.

Yours faithfully,  
Mayne Pharma Group Limited



Laura Loftus  
Company Secretary



**Mayne Pharma Group Limited**  
ABN 76 115 832 963  
[maynepharma.com](http://maynepharma.com)

**T** +61 8 8209 2666 **F** +61 8 8281 0284  
1538 Main North Road, Salisbury South, SA 5106 Australia  
PO Box 700, Salisbury, SA 5108 Australia

For personal use only

## RESULTS FOR ANNOUNCEMENT TO THE MARKET APPENDIX 4D – HALF YEAR REPORT

	% Change	Dec 2025 \$'000	Dec 2024 \$'000
Revenue from ordinary activities	(0.5%)	<b>212,070</b>	213,054
Profit / (loss) from continuing operations before income tax expense		<b>5,538</b>	(14,719)
Profit / (loss) from continuing operations after income tax expense		<b>(12,104)</b>	(19,970)
Profit / (loss) from discontinued activities after income tax		<b>(2,835)</b>	(5,575)
Profit / (loss) after income tax		<b>(14,939)</b>	(25,545)
<u>Attributable to:</u>			
Equity holders of the parent		(14,939)	(25,545)
Other comprehensive income after income tax expense		<b>(3,717)</b>	15,604
Total comprehensive income after income tax expense		<b>(18,656)</b>	(9,941)
<u>Attributable to:</u>			
Equity holders of the parent		(18,656)	(9,941)

Net tangible assets per ordinary share <sup>(1)</sup>	<b>(\$1.87)</b>	(\$1.69)
---	-----------------	----------

	2025 \$	2024 \$
Basic earnings (loss) per share continuing operations	(0.15)	(0.25)
Diluted earnings (loss) per share continuing operations	(0.15)	(0.25)
Final dividend in respect of the financial year ended 30 June per share	<b>Nil</b>	Nil
Interim dividend in respect of the period ended 31 December per share	<b>Nil</b>	Nil

(1) Net tangible assets include Right-of-use lease assets

Refer to the Directors' Report and the accompanying ASX announcement dated 23 February 2026 for a brief commentary on the results.

mayne **pharma**



## Half Year Financial Report

FOR THE HALF YEAR ENDED 31 DECEMBER 2025  
(PRIOR CORRESPONDING PERIOD: HALF YEAR ENDED 31 DECEMBER 2024)

For personal use only

## CONTENTS

CORPORATE INFORMATION .....	5
DIRECTORS' REPORT .....	6
AUDITOR'S INDEPENDENCE DECLARATION .....	12
CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME .....	13
CONSOLIDATED STATEMENT OF FINANCIAL POSITION .....	15
CONSOLIDATED STATEMENT OF CHANGES IN EQUITY .....	16
CONSOLIDATED STATEMENT OF CASH FLOW .....	17
NOTES TO THE FINANCIAL STATEMENTS .....	18
DIRECTORS' DECLARATION .....	40
AUDITOR'S INDEPENDENT REVIEW REPORT .....	41



## CORPORATE INFORMATION

<b>DIRECTORS:</b>	Prof Bruce Robinson, AC (Chair) Mr Patrick Blake Ms Ann Custin Mrs Anne Lockwood Dr Kathryn MacFarlane Mr David Petrie
<b>COMPANY SECRETARY:</b>	Ms Laura Loftus
<b>REGISTERED OFFICE</b>	1538 Main North Road Salisbury South South Australia 5106
<b>PRINCIPAL PLACES OF BUSINESS:</b>	1538 Main North Road Salisbury South South Australia 5106  3301 Benson Drive Suite 401 Raleigh North Carolina 27609 USA
<b>AUDITORS:</b>	BDO Audit Pty Ltd Collins Place Level 25, 35 Collins Street Melbourne VIC 3000
<b>SOLICITORS:</b>	Minter Ellison Lawyers Collins Arch Level 20, 447 Collins Street Melbourne VIC 3000
<b>SHARE REGISTRY:</b>	Computershare Investor Services Pty Ltd Yarra Falls 452 Johnston Street Abbotsford VIC 3067 Telephone: (03) 9415 4184 Facsimile: (03) 9473 2500
<b>BANKER:</b>	Westpac 150 Collins Street Melbourne VIC 3000
<b>ABN:</b>	76 115 832 963
<b>DOMICILE AND COUNTRY OF INCORPORATION:</b>	Australia
<b>LEGAL FORM OF ENTITY:</b>	Public company listed on the Australian Securities Exchange (MYX)

## DIRECTORS' REPORT

The Directors present their report, together with the financial statements, on the consolidated entity (referred to hereafter as the 'Consolidated Entity') consisting of Mayne Pharma Group Limited (referred to hereafter as the 'Company' or 'parent entity') and the entities it controlled at the end of, or during, the half-year ended 31 December 2025.

### DIRECTORS

The names of the Company's Directors in office during the half-year and until the date of this report are set out below. Directors were in office for this entire period unless otherwise noted.

Prof Bruce Robinson, AC (Chair effective from 14 January 2026)

Mr Patrick Blake

Ms Ann Custin

Mrs Anne Lockwood

Dr Kathryn MacFarlane

Mr David Petrie

Mr Frank Condella (retired from the Board and Chair role effective 14 January 2026)

Mr Shawn Patrick O'Brien (stepped down as CEO and Managing Director effective 20 February 2026 (US time)).

Mrs Anne Lockwood and Mr Patrick Blake will step down from the Board following the release of these results.

### REVIEW OF RESULTS

The Consolidated Entity reported revenue for the half year of \$212.1m. This compares to \$213.1m for the prior corresponding period (pcp).

The Consolidated Entity's net loss from continuing operations attributable to members of the Company for the half-year ended 31 December 2025 was a net loss of \$12.1m (half-year ended 31 December 2024: net loss \$20.0m).

Set out below is a summary of the financial performance attributable to Mayne Pharma shareholders for the six months ended 31 December 2025. This summary includes non-IFRS financial information that is stated excluding certain non-operating income and expense items. The results are set out this way as the Directors consider them to be a meaningful comparison from period to period. Earnings before interest tax, impairment, depreciation and amortisation (EBITDA) is used as a key measure of the earnings considered by management in operating the business and assessing performance.

	DEC 2025 \$M	DEC 2024 \$M	CHANGE ON PCP \$M
<b>SALES AND PROFIT</b>			
<b>Reported Revenue from continuing operations</b>	<b>212.1</b>	<b>213.1</b>	<b>(1.0)</b>
<b>Reported Gross profit from continuing operations</b>	<b>138.6</b>	<b>130.9</b>	<b>7.7</b>
<i>Reported Gross profit %</i>	<i>65.3%</i>	<i>61.4%</i>	
<b>Adjusted EBITDA</b>	<b>28.6</b>	<b>31.0</b>	<b>(2.4)</b>
Adjustments <sup>1</sup>	34.4	(4.9)	39.3
<b>Reported EBITDA from continuing operations</b>	<b>63.0</b>	<b>26.1</b>	<b>36.9</b>
Depreciation / Amortisation	(34.0)	(32.7)	(1.3)
<b>Reported Profit / (Loss) Before net finance expenses and Tax from continuing operations</b>	<b>29.0</b>	<b>(6.6)</b>	<b>35.6</b>
Net interest	(1.1)	0.2	(1.3)
Foreign exchanges gains/(losses) financing activities	(2.9)	9.3	(12.2)
Earn-out & deferred consideration liabilities discount unwind	(19.5)	(17.6)	(1.9)
<b>Reported Profit / (Loss) Before Tax from continuing operations</b>	<b>5.5</b>	<b>(14.7)</b>	<b>20.3</b>
Income tax credit / (expense)	(17.6)	(5.3)	(12.4)
<b>Reported Net Profit / (Loss) After Tax attributable to Mayne Pharma shareholders from continuing operations</b>	<b>(12.1)</b>	<b>(20.0)</b>	<b>7.9</b>

1. Current year adjustments are included in the table below.

The reconciliation of reported results and underlying results from continuing operations is as follows:

SALES AND PROFIT	REPORTED ATTRIBUTABLE TO MEMBERS DEC 2025 \$M	EARN-OUT REASSESSMENT <sup>(1)</sup> \$M	RESTRUCTURING <sup>(2)</sup> \$M	LITIGATION <sup>(3)</sup> \$M	DILIGENCE & BUSINESS DEVELOPMENT EXP <sup>(4)</sup> \$M	WH COGS <sup>(5)</sup> \$M	MARK TO MARKET REASSESSMENT DERIVATIVE <sup>(6)</sup> \$M	CONTINUING OPERATIONS UNDERLYING DEC 2025 \$M
<b>Revenue</b>	212.1							212.1
<b>Gross profit</b>	138.6					1.4		140.0
<i>Gross profit %</i>	65.3%							66.0%
<b>EBITDA</b>	<b>63.0</b>	(54.5)	2.3	1.9	21.3	1.4	(6.8)	<b>28.6</b>
Depreciation / Amortisation	(34.0)							(34.0)
<b>PBIT</b>	<b>29.0</b>	(54.5)	2.3	1.9	21.3	1.4	(6.8)	<b>(5.4)</b>
Net finance costs	(23.5)							(23.5)
<b>PBT</b>	<b>5.5</b>	(54.5)	2.3	1.9	21.3	1.4	(6.8)	<b>(28.9)</b>

(1) Earn-out and deferred consideration liabilities reassessment.

(2) Restructuring costs includes employee retention awards post the termination of the scheme with Cosette.

(3) Drug pricing and health care investigations, US Department of Justice and related litigation costs.

(4) Diligence and transaction costs including litigation costs related to the SID entered into with Cosette. The Supreme Court of New South Wales made an adverse costs order against Cosette following its decision in October 2025 requiring Cosette to pay Mayne Pharma's costs of the proceedings as agreed or assessed. Mayne Pharma is taking steps to enforce the costs order against Cosette, however the quantum of recovery has not yet been agreed or assessed or otherwise determined and as such is not recognised in this report.

(5) WH COGS – Mayne contributions to supplier to refine and further develop production process

(6) Mark to market / fair value reassessment of the conversion derivative relating to convertible notes.

The non IFRS financial information is unaudited. A more detailed analysis of the operating performance is included in the ASX Announcement and Results Presentation dated 23 February 2026.

## REVIEW OF OPERATIONS

The Group continues to develop and invest in existing assets as well as expand its disintermediation strategy to enhance growth opportunities.

Work on the Salisbury modernisation project, partly funded by a federal government grant, was completed during the period. The new encapsulator entered commercial production at the end of FY24, enabling the launch of KADIAN® 200mg in Canada. Installations include a bottling line and a high-speed blister packing line with serialisation capabilities. Official inauguration of the upgrade occurred in December 2025.

Pharmaceutical Benefits Scheme (PBS) approval for NEXTSTELLIS® in Australia was received in September 2025.

TWYNEO® and EPSOLAY® were launched in the United States during the half.

The Group recorded revenue of \$212.1m, down 0.5% on the prior corresponding period (pcp) and gross profit was \$138.6m, up 6% on pcp.

Gross profit reported as a percentage of sales revenue was 65.3% compared with 61.4% in the pcp.

The Consolidated Entity operates in three operating segments being International, Women's Health (formerly BPD) and Dermatology (formerly PPD). During a prior period, the Consolidated Entity sold the MCS segment and has therefore included MCS in discontinued operations (refer Note 5). The Consolidated Entity also sold the Retail Generics business effective 7 April 2023 which has also been disclosed as part of discontinued operations (refer Note 5). The segment note in the financial statements (Note 2) shows the sales, gross margin (GM), direct operating expenses (opex) and the direct contribution (being the GM less direct opex) for each segment on a continuing operations basis.

### **Women's Health**

The Women's Health Division distributes branded Women's Health products in the US. This division includes NEXTSTELLIS®, ANNOVERA®, BIJUVA® and IMVEXXY®.

Women's Health revenue increased 2% to \$96.5m (\$94.3m pcp) and gross profit decreased 1% to \$76.2m (\$76.9m pcp) for the period. Excluding the Women's Health COGS adjustment, Gross margin increased by 1%. Direct contribution decreased 8% to \$36.2m (\$39.3m pcp) due to increased investment in promotional expenses and Mayne's contribution to a supplier.

In USD terms, Women's Health revenue increased 1% to US\$63.3m (US\$62.3m pcp) and gross profit was US\$49.9m (US\$50.8m pcp) for the period. Direct contribution decreased 5% to US\$23.7m (US\$26.0m pcp). Key products driving revenue growth compared to the pcp were NEXTSTELLIS® (increase 2%) and IMVEXXY® (increase 2%). BIJUVA® revenue increased 23% with ANNOVERA® decreasing 9% compared to the pcp.

### **Dermatology**

The Dermatology Division distributes established dermatology products in the US.

Revenue decreased 3% to \$78.6m (\$81.4m pcp), gross profit increased 17% to \$51.1m (\$43.4m pcp) and direct contribution increased 35% to \$29.8m (\$22.1m pcp) for the period.

In USD terms, revenue decreased 4% to US\$51.5m (US\$53.8m pcp), gross profit increased 17% to US\$33.6m (US\$28.7m pcp) and direct contribution increased 35% to a US\$19.7m (US\$14.6m pcp) for the period.

Dermatology margin and contribution increases were driven by a change in the mix of products and by some effects of the Company's channel management (disintermediation). TWYNEO® and EPSOLAY® were launched during the period.

### **International**

International's revenue and gross profit are derived from the Australian manufacture and sale of branded and generic pharmaceutical products globally and the provision of contract development and manufacturing services to third party customers.

International revenue decreased 1% to \$36.9m (\$37.4m pcp), gross profit increased by 6% to \$11.3m (\$10.6m pcp) and direct contribution decreased 44% to \$2.1m (\$3.6m pcp) for the period.

NEXTSTELLIS® was approved for the Pharmaceutical Benefits Scheme (PBS) in Australia with effect from 1 October 2025 with additional investment in promotional activities occurring post PBS approval which had a negative impact on International's direct contribution.

The Salisbury facility capital works project was completed during the period with the official inauguration occurring in December 2025.

### **Expenses**

Net research, development, medical and regulatory affairs expense (total costs less costs capitalised) was \$12.7m, an increase in expense of \$2.8m on the pcp. The increase was due to post approval studies for ANNOVERA® and IMVEXXY®.

Marketing and distribution expenses were \$69.5m, a net increase of \$3.5m on the pcp. The increase includes investment in additional promotional expenditure and additional sales team members for both US and Australia.

Administration and other expenses were \$83.5m, an increase of \$19.6m on the pcp. The main reason for the increase was the litigation costs relating to the Cosette Scheme. This category includes non-cash and / or non-operating items such as:

- Amortisation of intangible assets \$30.0m (\$28.5m pcp);
- Reassessment of derivative fair value \$6.8m credit (\$0.2m credit pcp);
- Share based payments expense \$1.1m (\$2.1m pcp);
- Foreign exchange losses \$0.2m (\$1.0m fx loss pcp);
- Restructuring expenses \$2.3m (\$1.2m pcp);
- Diligence and transaction costs including litigation costs related to the SID entered into with Cosette. \$21.3m (\$2.5m pcp);  
The Supreme Court of New South Wales made an adverse costs order against Cosette following its decision in October

For personal use only



2025 requiring Cosette to pay Mayne Pharma's costs of the proceedings as agreed or assessed. Mayne Pharma is taking steps to enforce the costs order against Cosette, however the quantum of recovery has not yet been agreed or assessed or otherwise determined and as such is not recognised in this report; and

- Litigation costs \$1.9m (\$2.4m pcp).

Amortisation expense includes \$9.7m (pcp \$8.3m) for NEXTSTELLIS® and \$14.2m (pcp \$14.7m) for the assets acquired from TXMD. The balance of amortisation relates to Dermatology and International intangibles.

Excluding the non-cash and / or non-operating items, administration and other expenses increased by \$5.9m to \$32.2m. The main cause of the increase was the Paragraph iv litigation relating to IMVEXXY®.

There were no asset impairments in the current period or the pcp.

Finance expenses were \$25.0m, an increase of \$14.2m on the pcp. Included in net finance income/expenses are financing related foreign exchange losses of \$2.9m (pcp \$9.3m gains). Discount unwind on earnout and deferred consideration liabilities amounted to \$19.5m (pcp \$17.6m) in the current period.

The tax expense of \$16.8m comprised:

- Current period income tax expense for the six months to 31 December 2025 of \$3.6m;
- Prior year under provision of \$0.7m; and
- Expense of \$12.5m relating to the movement in net tax deferred tax assets and liabilities.

## REVIEW OF STATEMENT OF FINANCIAL POSITION

### *Cash*

Cash increased by \$7.5m compared to 30 June 2025.

Amounts invested in marketable securities (December 2025 \$0.1m, June 2025 \$40.6m) are not included in cash. Marketable securities are deposits in a money market fund with underlying investments in short term US government debt and repurchase obligations. Marketable securities are included in "Other Financial Assets" in the financial statements.

Refer to Review of Cash Flows for further commentary.

### *Inventory, receivables and trade payables*

The Company had a net cash investment in working capital of \$5.3m during the period. Working capital movements included reduction of inventory (\$3.5m), increases in trade receivables (\$15.4m), other current assets (\$14.5m) partially offset by an increase in trade and other payables (\$20.9m). The balance sheet and statement of cashflows include values relating to both continuing operations and discontinued operations. The balance sheet values are also impacted, compared to the pcp, by currency translation with the December 2025 AUD / USD exchange rate of 0.6701 compared to the June 2025 exchange rate of 0.6529.

### *Intangible assets*

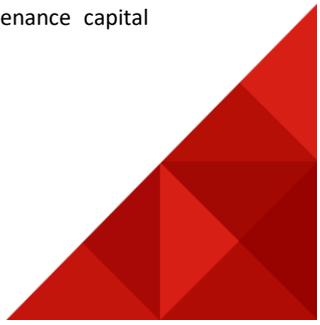
Intangible assets decreased by \$42.7m compared to the balance at 30 June 2025. The movement comprised of:

- An increase of \$0.2m for asset additions;
- A decrease of \$30.0m for amortisation; and
- A decrease of \$12.9m due to foreign currency translation with the AUD / USD exchange rate strengthening from 0.6529 at 30 June 2025 to 0.6701 at 31 December 2025. Most intangible assets are held in the US.

### *Property, plant & equipment*

Property, plant and equipment decreased by \$1.0m from the balance at 30 June 2025. The movement comprised of:

- An increase of \$1.3m for additions which included capital works programs and general site maintenance capital expenditure; and
- A decrease of \$2.3m for depreciation.



*Interest bearing liabilities.*

Interest bearing liabilities includes lease liabilities. Lease liabilities were \$4.4m at reporting date. Mayne Pharma issued convertible notes in December 2022 with total cash received of US\$27.95m. The convertible notes liability has been split into two components – the loan liability (\$37.1m included in interest bearing liabilities at reporting date) and the conversion option (derivative) component (initially recognised at \$9.7m and subsequently restated at fair value each reporting period – which is included in the balance sheet as “Other financial liabilities”).

*Other financial liabilities*

Other financial liabilities decreased by \$71.4m from 30 June 2025 as a result of:

- An increase of \$19.5m due to the unwinding of the discount for the various earn-out liabilities and deferred consideration liabilities;
- A decrease of \$6.8m due to fair value restatement of the option derivative relating to convertible notes;
- A decrease of \$54.5m due to re-assessments of various earn-out and deferred consideration liabilities;
- A decrease of \$20.7m due to payments made for earn-outs and deferred settlements; and
- A decrease relating to foreign exchange and foreign currency translation of \$9.0m.

**REVIEW OF CASH FLOWS**

Cash at 31 December 2025 was \$67.4m, representing an increase of \$7.6m from 30 June 2025. Amounts invested in marketable securities (December 2025 \$0.1m, June 2025 \$40.6m) are not included in cash. Marketable securities are deposits in a money market fund with underlying investments in short term US government debt and repurchase obligations. Marketable securities are included in “Other Financial Assets” in the financial statements.

A summary of operating cash flows is as follows:

	Dec 2025 \$M	Dec 2024 \$M
Operating cash flow before working capital movements	17.1	22.1
Working capital (investment) / release	(5.3)	1.1
Net Operating cash flows before Cosette scheme and litigation costs and Class Action settlement	11.8	23.2
Cosette scheme and litigation costs	(20.7)	(2.9)
Class Action settlement (net of insurance)	-	(33.3)
<b>Net Operating cash flows</b>	<b>(8.9)</b>	<b>(13.0)</b>
Less estimated cashflows relating to discontinued operations outflows / (inflows)	5.1	5.6
Estimated net operating cashflows from continuing operations	(3.8)	(7.4)

Operating cash flow was impacted by the Cosette Scheme litigation and discontinued operations including payments for certain operating expenses and payments for gross-to-net liabilities for the divested Retail Generics business. Excluding these items operating cashflow from continuing operations was \$16.9m. In relation to Cosette litigation costs, the Supreme Court of New South Wales made an adverse costs order against Cosette following its decision in October 2025 requiring Cosette to pay Mayne Pharma’s costs of the proceedings as agreed or assessed. Mayne Pharma is taking steps to enforce the costs order against Cosette, however the quantum of recovery has not yet been agreed or assessed or otherwise determined and as such is not recognised in this report.

	Dec 2025 \$M	Dec 2024 \$M
Investing cash flows	18.2	(45.0)

Notable cash flows during the period included:

- \$1.3m payments for net capital expenditure;
- \$40.4m withdrawal from marketable securities; and
- Earn-out and deferred settlement payments totalling \$20.9m which included \$3.1m paid to Catalent as a result of the MCS sale.

For personal use only



	Dec 2025 \$M	Dec 2024 \$M
Financing cash flows	(0.9)	(0.3)

Notable cash flows during the period included:

- Net interest receipts \$0.8m; and
- Lease payments (right-of-use) assets \$1.7m.

#### DIVIDEND

No dividend was declared or paid for the period ended 31 December 2025.

#### ROUNDING

The Company is of a kind referred to in ASIC Legislative Instrument 2016/191 issued by the Australian Securities and Investments Commission, relating to the “rounding off” of amounts in this report and in the financial report. Amounts in this report and in the financial report have been rounded off in accordance with that Legislative Instrument to the nearest thousand dollars or, in certain cases, to the nearest dollar.

#### AUDITOR’S INDEPENDENCE DECLARATION

The Auditor’s independence declaration is included on page 12 of the Financial Report.

#### EVENTS SUBSEQUENT TO REPORTING DATE

On 15 January 2026, Cosette filed an appeal against Justice Black’s decision in the Supreme Court of New South Wales, Court of Appeal. The appeal has been listed for a 2-day hearing on 2 and 3 June 2026.

On 18 February 2026, Mayne Pharma commenced proceedings in the Supreme Court of New South Wales against Cosette Pharmaceuticals, Inc, Cosette Pharmaceuticals Holdings, Inc, Avista Capital Holdings, LP trading as Avista Healthcare Partners (Avista) and David Burgstahler (the Managing Partner and CEO of Avista) seeking substantial damages on behalf of Mayne Pharma shareholders against Cosette for breach of the Scheme Implementation Deed (SID) and against the other defendants for inducing Cosette’s breach of the SID. Mayne Pharma is also seeking substantial damages on its own behalf against the defendants.

Mr Shawn Patrick O’Brien stepped down as Chief Executive Officer and Managing Director effective 20 February 2026 (US time) and Mr Aaron Gray (previously Mayne Pharma’s Chief Financial Officer) was appointed Chief Executive Officer as part of Mayne Pharma’s planned leadership transition. Refer Mayne Pharma’s ASX announcement dated 23 February 2026.

No other matter or circumstance has arisen since the reporting date which is not otherwise reflected in this report that significantly affected or may significantly affect the operations of the Consolidated Entity.

Signed in accordance with a resolution of the Directors.

Dated this 23<sup>rd</sup> day of February 2026.



**Bruce Robinson, AC**  
Independent Chair

For personal use only



## AUDITOR'S INDEPENDENCE DECLARATION



Tel: +61 3 9603 1700  
Fax: +61 3 9602 3870  
www.bdo.com.au

Collins Place  
Level 25, 35 Collins Street  
Melbourne VIC 3000  
GPO Box 5099 Melbourne VIC 3001  
Australia

### DECLARATION OF INDEPENDENCE BY BENJAMIN LEE TO THE DIRECTORS OF MAYNE PHARMA GROUP LIMITED

As lead auditor for the review of Mayne Pharma Group Limited for the half-year ended 31 December 2025, I declare that, to the best of my knowledge and belief, there have been:

1. No contraventions of the auditor independence requirements of the *Corporations Act 2001* in relation to the review; and
2. No contraventions of any applicable code of professional conduct in relation to the review.

This declaration is in respect of Mayne Pharma Group Limited and the entities it controlled during the period.



Benjamin Lee  
Director

BDO Audit Pty Ltd

Melbourne, 23 February 2026

For personal use only



## CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

FOR THE HALF-YEAR ENDED 31 DECEMBER 2025

	Notes	31 December 2025 \$'000	31 December 2024 \$'000
<b>Continuing operations</b>			
Sale of goods		192,862	193,722
Services revenue		16,472	18,495
Royalties revenue		2,736	641
License fees		-	196
<b>Revenue</b>	2	<b>212,070</b>	213,054
Cost of sales	2, 3	(73,491)	(82,195)
<b>Gross profit</b>		<b>138,579</b>	130,859
Interest income		1,522	2,696
Other income		192	1,339
Earn-out and deferred consideration liabilities reassessments		54,509	1,019
Research, development, medical and regulatory affairs expenses		(12,713)	(9,886)
Marketing and distribution expenses		(69,487)	(65,985)
Administrative and other expenses	3	(82,074)	(63,944)
Finance expenses - other	3	(2,614)	(2,482)
Foreign exchange (losses) / gains related to financing activities	3	(2,853)	9,302
Finance expenses – discount unwind related to earn-outs & deferred consideration liabilities	3	(19,523)	(17,637)
<b>Net profit / (loss) before income tax</b>		<b>5,538</b>	(14,719)
Income tax credit / (expense)	4	(17,642)	(5,251)
<b>Net (loss) / profit for the period from continuing operations</b>		<b>(12,104)</b>	(19,970)
<b>Discontinued operations</b>			
Profit / (loss) after tax for the period from discontinued operations	5	(2,835)	(5,575)
<b>Net (loss) / profit for the period attributable to equity holders of the Parent</b>		<b>(14,939)</b>	(25,545)

## CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME (continued)

FOR THE HALF-YEAR ENDED 31 DECEMBER 2025

Notes	31 December 2025 \$'000	31 December 2024 \$'000
<b>Other comprehensive income for the period, net of tax</b>		
<u>Items which may be reclassified to profit/loss</u>		
Exchange differences on translation	(4,661)	18,307
Income tax effect	944	(2,703)
<b>Total comprehensive income for the period</b>	<b>(18,656)</b>	<b>(9,941)</b>
Attributable to:		
Equity holders of the Parent	(18,656)	(9,941)
	<b>(18,656)</b>	<b>(9,941)</b>
Basic earnings per share	(18.8) cents	(32.3) cents
Diluted earnings per share	(18.8) cents	(32.3) cents
Earnings per share from continuing operations:		
Basic earnings (loss) per share from continuing operations	(15.3) cents	(25.3) cents
Diluted earnings (loss) per share from continuing operations	(15.3) cents	(25.3) cents

**This statement should be read in conjunction with the accompanying notes to the financial statements**



## CONSOLIDATED STATEMENT OF FINANCIAL POSITION

AS AT 31 DECEMBER 2025

	Notes	31 December 2025 \$'000	30 June 2025 \$'000
<b>Current assets</b>			
Cash and cash equivalents	6	67,347	59,839
Trade and other receivables	7	191,449	180,643
Inventories	8	47,496	50,561
Income tax receivable		1,140	1,257
Other financial assets (includes marketable securities)		2,359	42,934
Other current assets	9	31,334	17,558
<b>Total current assets</b>		<b>341,125</b>	<b>352,792</b>
<b>Non-current assets</b>			
Other non-current assets	9	15,070	15,409
Property, plant and equipment	10	52,072	53,142
Right-of-use assets		5,040	5,727
Deferred tax assets	4	24,129	41,764
Intangible assets	11	503,114	545,771
<b>Total non-current assets</b>		<b>599,425</b>	<b>661,813</b>
<b>Total assets</b>		<b>940,550</b>	<b>1,014,605</b>
<b>Current liabilities</b>			
Trade and other payables	12	190,569	174,304
Interest-bearing loans and borrowings	13	40,312	38,616
Other financial liabilities	14	15,965	37,657
Provisions	15	10,538	10,434
<b>Total current liabilities</b>		<b>257,384</b>	<b>261,011</b>
<b>Non-current liabilities</b>			
Interest-bearing loans and borrowings	13	2,153	2,655
Other financial liabilities	14	321,678	371,404
Deferred tax liabilities	4	6,151	8,795
Provisions	15	477	457
<b>Total non-current liabilities</b>		<b>330,459</b>	<b>383,311</b>
<b>Total liabilities</b>		<b>587,843</b>	<b>644,322</b>
<b>Net assets</b>		<b>352,707</b>	<b>370,283</b>
<b>Equity</b>			
Contributed equity	16	1,229,773	1,225,979
Reserves		178,855	185,286
Accumulated Losses		(1,055,921)	(1,040,982)
<b>Total equity</b>		<b>352,707</b>	<b>370,283</b>

This statement should be read in conjunction with the accompanying notes to the financial statements.

For personal use only

## CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

FOR THE HALF-YEAR ENDED 31 DECEMBER 2025

	Contributed Equity \$'000	Share-Based Payment Reserve \$'000	Foreign Currency Translation Reserve \$'000	Other Reserve \$'000	Accumulated losses \$'000	Total Equity \$'000
Balance at 1 July 2025	1,225,979	60,960	124,326	-	(1,040,982)	370,283
Profit / (loss) for the period	-	-	-	-	(14,939)	(14,939)
Other comprehensive income						
Foreign exchange translation (net of tax)	-	-	(3,717)	-	-	(3,717)
Total comprehensive income	-	-	(3,717)	-	(14,939)	(18,656)
<i>Transactions with owners in capacity as owners</i>						
Taxes paid relating to RSU's vesting	-	-	-	-	-	-
Equity contribution re LTI program	3,794	(3,794)	-	-	-	-
Share-based payments	-	1,080	-	-	-	1,080
Balance at 31 December 2025	1,229,773	58,246	120,609	-	(1,055,921)	352,707
Balance at 1 July 2024	1,224,224	58,584	118,526	(3,143)	(944,003)	454,188
Profit / (loss) for the period	-	-	-	-	(25,545)	(25,545)
Other comprehensive income						
Foreign exchange translation (net of tax)	-	-	15,604	-	-	15,604
Total comprehensive income	-	-	15,604	-	(25,545)	(9,941)
<i>Transactions with owners in capacity as owners</i>						
Taxes paid relating to RSU's vesting	(148)	-	-	-	-	(148)
Equity contribution re LTI program	1,579	(1,579)	-	-	-	-
Share-based payments	-	2,105	-	-	-	2,105
Balance at 31 December 2024	1,225,655	59,110	134,130	(3,143)	(969,548)	446,204

This statement should be read in conjunction with the accompanying notes to the financial statements.

## CONSOLIDATED STATEMENT OF CASH FLOW

FOR THE HALF-YEAR ENDED 31 DECEMBER 2025

	Notes	31 December 2025 \$'000	31 December 2024 \$'000
<b>Cash flows from operating activities</b>			
Receipts from customers		372,501	381,902
Payments to suppliers and employees		(359,565)	(358,478)
Tax paid		(1,066)	(216)
Net cash flows from operating activities before Class Action settlement		11,870	23,208
Scheme costs including litigation		(20,721)	(2,938)
Class Action settlement (net of insurance)		-	(33,300)
<b>Net cash flows from / (used in) operating activities</b>	6	<b>(8,851)</b>	<b>(13,030)</b>
<b>Cash flows from investing activities</b>			
Payments for plant and equipment		(1,309)	(6,872)
Redemption of marketable securities		40,371	-
Investment in marketable securities		-	(27,215)
Payments for intangible assets		(214)	(831)
Earn-out and deferred settlement payments		(20,666)	(10,076)
<b>Net cash flows from / (used in) investing activities</b>		<b>18,182</b>	<b>(44,994)</b>
<b>Cash flows from financing activities</b>			
Payments of interest		(736)	(742)
Receipts of interest		1,522	2,696
Payment of lease liabilities (right-of-use assets)		(1,719)	(2,066)
Taxes paid relating to RSU's vesting		-	(148)
<b>Net cash flows from / (used in) financing activities</b>		<b>(933)</b>	<b>(260)</b>
<b>Net increase/(decrease) in cash and cash equivalents</b>			
		8,398	(58,284)
Cash and cash equivalents at beginning of period		59,839	110,068
Effect of foreign exchange changes on cash held in foreign currencies		(889)	1,926
<b>Cash and cash equivalents at end of period</b>	6	<b>67,347</b>	<b>53,710</b>

This statement should be read in conjunction with the accompanying notes to the financial statements.

## NOTES TO THE FINANCIAL STATEMENTS

FOR THE HALF-YEAR ENDED 31 DECEMBER 2025

### 1. BASIS OF PREPARATION AND ACCOUNTING POLICIES

#### (a) Basis of preparation

The financial report for the half-year ended 31 December 2025 has been prepared in accordance with AASB 134 *Interim Financial Reporting* and the *Corporations Act 2001*.

The half-year financial report does not include all notes of the type normally included within the annual financial report and therefore cannot be expected to provide as full an understanding of the financial performance, financial position and financing and investing activities of the Consolidated Entity as the annual financial report.

Under *AASB 134 Interim Financial Reporting*, measurement is generally made on an annual reporting period to date basis. However, it is recognised that the interim period is part of a larger annual reporting period not an independent reporting period.

It is recommended that the half-year financial report be read in conjunction with the annual report for the year ended 30 June 2025 and considered together with any public announcements made by Mayne Pharma Group Limited during the half-year ended 31 December 2025 in accordance with the continuous disclosure obligations of the *ASX Listing Rules*.

#### (b) Change in presentation

Where required, items in the December 2024 and June 2025 comparatives have been reclassified to reflect the current presentation and enable better comparison between periods.

#### (c) Changes in accounting policy and adoption of new accounting standards

The accounting policies adopted in the preparation of the interim consolidated financial statements are consistent with those followed in the preparation of the Group's annual consolidated financial statements for the year ended 30 June 2025.

No other new and/or amended standards that were effective for the Group as of 1 July 2025 had a material impact on the financial statements of the Group as they are either not relevant to the Group's activities or require accounting which is consistent with the Group's current accounting policies.

#### (d) New accounting standards and interpretations

At the date of authorisation of the financial report, no Standards and Interpretations relevant to the Group were issued but not yet effective.

#### (e) Significant judgements and estimates

The preparation of the financial statements requires management to make judgements, estimates and assumptions that affect the reported amounts in the financial statements. Management continually evaluates these judgements and estimates in relation to assets, liabilities, contingent liabilities, revenue and expenses. Management bases these judgements and estimates on historical experience and on other various factors it believes to be reasonable under the circumstances, the result of which form the basis of the carrying values of assets and liabilities that are not apparent from other sources. Actual results may differ from these estimates under different assumptions and conditions.

### 2. SEGMENT REPORTING

The Group has identified its operating segments based on the internal reports that are reviewed and used by the CEO (as the chief operating decision maker) in assessing performance and in determining the allocation of resources.



The operating segments are identified by management based on the nature of revenue flows and responsibility for those revenues. Discrete financial information about each of these operating segments is reported to the chief operating decision maker on at least a monthly basis.

The Consolidated Entity operates in three operating segments being Dermatology, Women's Health and International. During a prior period, the Consolidated Entity sold the Metrics Contract Services segment (MCS) and the Retail Generics business (which previously formed part of the PPD segment) and has therefore included MCS and Retail Generics in discontinued operations (refer Note 5).

#### Dermatology Division (formerly PPD)

The Dermatology Division distributes dermatology products (branded and generic) in the US on a portfolio basis.

#### Women's Health Division (formerly BPD)

The Women's Health Division distributes branded women's health products in the US.

#### International

The International operating segment's revenues and gross profit are derived principally from the Australian manufacture and sale of branded and generic pharmaceutical products globally and the provision of contract development and manufacturing services to third party customers.

	Dermatology \$'000	Women's Health \$'000	International \$'000	Total Consolidated \$'000
<b>Half Year ended 31 December 2025</b>				
Sale of goods	78,618	96,529	17,715	192,862
Services income	-	-	16,472	16,472
Royalty income	-	-	2,736	2,736
Licence fee income	-	-	-	-
Revenue	78,618	96,529	36,923	212,070
Cost of sales	(27,537)	(20,299)	(25,655)	(73,491)
Gross profit	51,081	76,230	11,268	138,579
Direct operating expenses	(21,300)	(39,984)	(9,211) <sup>1</sup>	(70,495)
Direct contribution	29,781	36,246	2,057	68,084
Other income				192
Earn-out and deferred consideration liabilities reassessments				54,509
Amortisation of intangible assets				(29,958)
Finance expenses (net) (includes discount unwind relating to earn-outs)				(23,468)
Unallocated / indirect expenses (includes derivative value reassessment, litigation costs etc)				(63,821)
Profit / (loss) before income tax				5,538
Income tax (expense) / benefit				(17,642)
Net profit / (loss) for the period from continuing operations				(12,104)

Note: (1) Direct operating expenses for the International segment include finance, HR and IT expenses whereas the US segments share such services and hence no allocation for such services has been made to the Dermatology and Women's Health segments.

	Dermatology \$'000	Women's Health \$'000	International \$'000	Total Consolidated \$'000
<b>Half Year ended 31 December 2024</b>				
Sale of goods	81,386	94,286	18,050	193,722
Services income	-	-	18,495	18,495
Royalty income	-	-	641	641
Licence fee income	-	-	196	196
Revenue	81,386	94,286	37,382	213,054
Cost of sales	(37,981)	(17,419)	(26,795)	(82,195)
Gross profit	43,405	76,867	10,587	130,859
Direct operating expenses	(21,353)	(37,605)	(6,945) <sup>1</sup>	(65,903)
Direct contribution	22,052	39,262	3,642	64,956
Other income				1,339
Earn-out and deferred consideration liabilities reassessments				1,019
Amortisation of intangible assets				(28,500)
Finance expenses (net) (includes discount unwind relating to earn-outs)				(8,121)
Unallocated / indirect expenses (includes derivative value reassessment)				(45,412)
Profit / (loss) before income tax				(14,719)
Income tax (expense) / benefit				(5,251)
Net profit / (loss) for the period from continuing operations				(19,970)

Note: (1) Direct operating expenses for the International segment include finance, HR and IT expenses whereas the US segments share such services and hence no allocation for such services has been made to the Dermatology and Women's Health segments.

	31 December 2025 \$'000	31 December 2024 \$'000
<i>Geographical segment information</i>		
Australia	16,146	22,781
United States	177,722	178,278
Other	18,202	11,995
<b>Total external revenue</b>	<b>212,070</b>	213,054

	31 December 2025 \$'000	31 December 2024 \$'000
<i>Revenue from customer contracts</i>		
Recognised at a point in time	195,598	194,559
Recognised over time	16,472	18,495
<b>Total external revenue from customer contracts</b>	<b>212,070</b>	213,054

	31 December 2025 \$'000	31 December 2024 \$'000
<i>Revenue by product group / service</i>		
Third party contract services and manufacturing	16,472	18,495
Generic and branded products	192,862	193,722
Other revenue	2,736	837
<b>Total external revenue</b>	<b>212,070</b>	213,054

### 3. EXPENSES

	31 December 2025 \$'000	31 December 2024 \$'000
<b>Finance expenses</b>		
Interest expense	519	546
Amortisation of borrowing costs	1,899	1,710
Interest expense – right-of-use asset lease liabilities	196	226
	2,614	2,482
Change in fair value attributable to the unwinding of the discounting of earn-out and deferred consideration liabilities	19,523	17,637
Foreign exchange losses / (gains) relating to funding activities	2,853	(9,302)
<b>Total finance expense</b>	<b>24,990</b>	<b>10,817</b>
Depreciation property, plant & equipment	2,341	2,346
Depreciation right-of-use assets	1,670	1,809
<b>Total Depreciation (continuing operations)</b>	<b>4,011</b>	<b>4,155</b>
<b>Depreciation is included in the following categories in the Statement of Profit Loss –</b>		
Cost of sales	2,194	2,178
Research, development, medical and regulatory affairs expenses	142	171
Marketing and distribution expenses	1,242	1,353
Administrative and other expenses	433	453
<b>Total Depreciation (continuing operations)</b>	<b>4,011</b>	<b>4,155</b>
<b>Cost of sales include the following:</b>		
Inventory write-offs	-	569
Provision for inventory obsolescence	1,823	925
<b>Employee benefits expense <sup>(1)</sup></b>		
Wages and salaries	50,048	47,754
Superannuation expense	2,766	2,513
Share-based payments expense	1,080	2,105
Other employee benefits expense	2,277	2,360
<b>Total employee benefits expense (continuing operations)</b>	<b>56,171</b>	<b>54,732</b>
<b>Administration and other expenses include the following:</b>		
Litigation costs	1,908	2,423
Diligence, business development and related litigation expenses	21,263	2,520
Share-based payments expense	1,080	2,105
Amortisation of intangible assets	29,958	28,500
Mark to market of derivative related to convertible note	(6,786)	(153)
Foreign exchange losses / (gains)	152	999
Restructuring expenses <sup>(2)</sup>	2,262	1,164
All other administration and other expenses	32,237	26,386
<b>Total Administration and other expenses</b>	<b>82,074</b>	<b>63,944</b>

The above expenses relate to continuing operations only.

Notes: (1) Employee benefit expense is included in various expense categories and cost of sales.

(2) Restructuring costs includes employee retention awards post the termination of the scheme with Cosette.

#### 4. INCOME TAX

(a) The major components of income tax expense are:

	31 December 2025 \$'000	31 December 2024 \$'000
<i>Current income tax</i>		
Current income tax	(3,546)	(2,428)
Adjustment in respect of current income tax of previous years	(730)	(84)
<i>Deferred income tax</i>		
Relating to movement in net tax deferred tax assets and liabilities	(12,534)	(1,102)
Income tax credit / (expense) in the consolidated statement of profit or loss and other comprehensive income	<b>(16,810)</b>	<b>(3,614)</b>

(b) Numerical reconciliation between aggregate tax expense recognised in the consolidated statement of profit or loss and other comprehensive income and tax expense calculated per the statutory income tax rate

	31 December 2025 \$'000	31 December 2024 \$'000
The prima facie tax on operating (loss) / profit differs from the income tax provided in the accounts as follows:		
Profit / (loss) before income tax (includes discontinued operations)	1,871	(21,931)
Prima facie tax credit / (expense) at 30%	(562)	6,579
Under provision in respect of prior years	(730)	(84)
Income assessable for income tax purposes	(1,440)	-
Income non-assessable for income tax purposes	2,036	-
Non-deductible expenses for tax purposes		
Amortisation	(1,021)	(964)
Share-based payments	(148)	(201)
Other non-deductible expenses	(673)	(289)
Effect of different tax rate in US	2,474	(3,128)
US State taxes	(1,361)	1,808
Restatement of DTA re changes to US state tax rates	(99)	16,171
Deferred tax asset derecognition adjustment	(15,286)	(23,506)
Income tax credit / (expense)	<b>(16,810)</b>	<b>(3,614)</b>
Income tax credit / (expense) from continuing operations	(17,642)	(5,251)
Income tax credit / (expense) from discontinued operations	832	1,637
Income tax credit / (expense)	<b>(16,810)</b>	<b>(3,614)</b>

For personal use only



(c) Recognised deferred tax assets and liabilities

	31 December 2025 \$'000	30 June 2025 \$'000
<b>Deferred tax assets</b>		
Intangible assets	53,182	60,428
Provisions	5,792	5,776
Payables	31,762	31,487
Carry forward tax losses and R&D credits	184,025	188,001
Expenditure deferred and amortised for income tax purposes	7,529	2,043
Inventory	1,153	1,662
US State taxes	55,799	58,422
Property, plant and equipment	1,366	1,711
Other	(26)	1,062
Less deferred tax asset not recognised	(316,590)	(309,590)
	<b>23,992</b>	<b>41,002</b>
<b>Reconciliation to the Statement of Financial Position</b>		
Total Deferred Tax Assets	23,992	41,002
Set off against Deferred Tax Liabilities	137	762
<b>Net Deferred Tax Assets<sup>(1)</sup></b>	<b>24,129</b>	<b>41,764</b>
<b>Deferred tax liabilities</b>		
Property, plant and equipment	383	339
Intangible assets	992	1,106
Unrealised foreign exchange gains	4,033	6,041
US State taxes	77	61
Other	529	486
	<b>6,014</b>	<b>8,033</b>
<b>Reconciliation to the Statement of Financial Position</b>		
Total Deferred Tax Liabilities	6,014	8,033
Set off against Deferred Tax Assets	137	762
<b>Net Deferred Tax Liabilities<sup>(2)</sup></b>	<b>6,151</b>	<b>8,795</b>

Notes: (1) Represents Australian and US Deferred Tax Assets that cannot be offset against US Deferred Tax Liabilities.  
(2) Represents US Deferred Tax Liabilities that cannot be offset against Australian Deferred Tax Assets.

Deferred tax assets and deferred tax liabilities are presented based on their respective tax jurisdictions.

Temporary differences associated with investments in the Group's subsidiaries have not been recognised.

Deferred tax assets and liabilities are not recognised for temporary difference relating to investments in subsidiaries to the extent that the Group is able to control the timing of the reversal of the temporary differences and it is probable that they will not reverse in the foreseeable future.

Unrecognised deferred income tax assets are reassessed at each reporting date and are recognised to the extent that it has become probable that future taxable profit will allow the deferred tax asset to be recovered. In the current period, when this assessment occurred, it indicated that, due to the expected length of time needed to recover the deferred tax asset, it continued to be not probable that all the deferred tax assets would be recovered and hence a write-down to the expected probable recoverable amount was made in the current period of \$15.3m.

## 5. DISCONTINUED OPERATIONS

On 4 October 2022 Mayne Pharma completed the sale of the MCS business. MCS was previously reported as a standalone operating segment.

The results of discontinued operations were as follows –

	31 December 2025 \$'000	31 December 2024 \$'000
Estimated operating cashflow relating to discontinued operations MCS	-	-
Investing cashflows related to discontinued operations		
Contracted payments to purchaser of MCS (included in Earnout payments in the Statement of Cashflows)	(3,066)	(3,723)

There were no material financing cashflows specific to discontinued operations.

Following the divestment of the MCS business, the Company paid an overhead recovery contribution to the purchaser (classified as an earn-out) that was negotiated as part of the sale agreement. These earnout payments flow through investing cashflows, they are fixed payments, quarterly, and the last payment occurred in H1 of FY26.

On 7 April 2023, Mayne Pharma completed the sale of the Retail Generics (RGx) business. The Retail Generics business was previously included as part of the PPD operating segment.

The results of discontinued operations – Retail Generics were as follows -

	31 December 2025 \$'000	31 December 2024 \$'000
Sales revenue	(3,641)	(5,976)
Cost of sales	(2)	(1,062)
Gross Margin	(3,643)	(7,038)
Operating expenses	(24)	(174)
Operating profit / (loss) before tax from discontinued operations	(3,667)	(7,212)
Tax benefit / (expense)	832	1,637
Profit / (loss) for the period from discontinued operations – Retail Generics	(2,835)	(5,575)
Estimated operating cashflow relating to discontinued operations Retail Generics	(5,123)	(5,589)

The transaction to divest the RGx business included transfer of certain channel liabilities for product sold into the channel that had not yet been dispensed. Those liabilities can be long-lived with the longest being product returns. Wholesalers may return product up to 12 months after expiration of the product, therefore some product having a long shelf life (36 months) can be returned as long as 48 months after the sale of that product.

Since the divestment, both Mayne Pharma and Dr Reddy's Laboratories (DRL) have paid charges for this product inventory. Net sales adjustments include accruals for product returns.

	31 December 2025 \$'000	31 December 2024 \$'000
<b>Profit / (loss) after tax for the period from discontinued operations</b>	(2,835)	(5,575)
	31 December 2025 \$	31 December 2024 \$
Basic and diluted earnings per share discontinued operations	(0.04)	(0.07)

For personal use only

## 6. CASH AND CASH EQUIVALENTS

(a) For the consolidated statement of cash flows, cash and cash equivalents are comprised of the following:

	31 December 2025 \$'000	30 June 2025 \$'000
Cash at bank and in hand	67,347	59,839

(b) Reconciliation of net profit after income tax to net cash flow from operating activities

	31 December 2025 \$'000	31 December 2024 \$'000
Net profit / (loss) after income tax	(14,939)	(25,545)
Adjustments for:		
Depreciation and amortisation	35,869	34,365
Share-based payments	1,080	2,105
Earn-out and deferred consideration liability reassessments	(54,509)	(1,019)
Discount unwind earn-out and deferred consideration liabilities	19,523	17,636
Derivative value restatement	(6,786)	(153)
Other finance (income) / expenses	(783)	(1,924)
Net unrealised foreign exchange differences	2,417	(8,002)
Non-cash provisions – inventory	(1,174)	(1,707)
Changes in tax balances:		
Decrease / (Increase) in deferred tax assets	13,765	(984)
(Decrease) / Increase in current and deferred tax liabilities	1,979	4,384
Operating cash flows before working capital movements	(3,558)	19,156
Changes in working capital:		
Decrease / (Increase) in receivables	(15,406)	6,456
Decrease / (Increase) in inventories	3,482	17,856
(Increase) in other assets	(14,535)	(1,508)
(Decrease) / Increase in creditors	20,934	(20,175)
Increase / (Decrease) in provisions	232	(1,515)
Total working capital movements	(5,293)	1,114
Changes in other receivables and other payables relating to Class Action settlement (net)	-	(33,300)
Net cash flow from operating activities	(8,851)	(13,030)

## 7. TRADE AND OTHER RECEIVABLES

	31 December 2025 \$'000	30 June 2025 \$'000
Trade receivables (net of charge-backs)	171,642	162,919
Trade receivables – profit share	3,214	2,642
Provision for impairment	(917)	(942)
Other receivables	17,510	16,024
	191,449	180,643

For personal use only

## 8. INVENTORIES

	31 December 2025 \$'000	30 June 2025 \$'000
Raw materials and stores at cost	12,874	10,286
Work in progress at cost	5,373	5,955
Finished goods at lower of cost and net realisable value	29,249	34,320
	<b>47,496</b>	<b>50,561</b>

The Group has recognised provisions at reporting date for obsolescence and net realisable value adjustments of \$3,501,000 (30 June 2025: \$4,331,000).

## 9. OTHER ASSETS

	31 December 2025 \$'000	30 June 2025 \$'000
<b>Current</b>		
Deposits for gross-to-net sales arrangements	2,080	1,189
Prepaid gross-to-net costs	7,303	-
Other prepayments	21,951	16,369
	<b>31,334</b>	<b>17,558</b>
<b>Non-Current</b>		
Deposits for various commercial contracts	15,070	15,409
	<b>15,070</b>	<b>15,409</b>

## 10. PROPERTY, PLANT AND EQUIPMENT

	LAND \$'000	BUILDINGS \$'000	PLANT AND EQUIPMENT \$'000	CAPITAL WORKS IN PROGRESS \$'000	TOTAL \$'000
<b>Six months ended 31 December 2025</b>					
Balance at beginning of period net of accumulated depreciation	2,981	14,343	21,779	14,039	53,142
Additions	-	-	-	1,336	1,336
Transfers from capital under construction	-	-	4,225	(4,225)	-
Depreciation charge for year	-	(249)	(2,093)	-	(2,342)
Disposals	-	-	(28)	-	(28)
Exchange differences	-	-	(36)	-	(36)
Balance at end of year net of accumulated depreciation	<b>2,981</b>	<b>14,094</b>	<b>23,847</b>	<b>11,150</b>	<b>52,072</b>
<b>As at 31 December 2025</b>					
At cost	2,981	19,924	67,719	16,030	106,654
Accumulated depreciation	-	(5,830)	(43,872)	-	(49,702)
Accumulated impairments	-	-	-	(4,880)	(4,880)
Net carrying amount	<b>2,981</b>	<b>14,094</b>	<b>23,847</b>	<b>11,150</b>	<b>52,072</b>

For personal use only

## 11. INTANGIBLE ASSETS

	Customer Contracts, Customer Relationships Product Rights & Intellectual Property \$'000	Development Expenditure \$'000	Marketing & Distribution Rights \$'000	Trade Names \$'000	Total \$'000
<b>Six months ended 31 December 2025</b>					
Balance at beginning of the period net of accumulated amortisation and accumulated impairments	527,950	3,665	1,185	12,971	545,771
Additions	-	214	-	-	214
Amortisation	(27,423)	(592)	(259)	(1,684)	(29,958)
Exchange differences	(12,913)	-	-	-	(12,913)
Balance at end of period net of accumulated amortisation and accumulated impairments	487,614	3,287	926	11,287	503,114
<b>As at 31 December 2025</b>					
Cost	853,204	40,897	29,659	63,778	987,538
Accumulated amortisation	(275,774)	(12,981)	(14,717)	(48,186)	(351,658)
Accumulated impairments	(89,816)	(24,629)	(14,016)	(4,305)	(132,766)
Net carrying amount	487,614	3,287	926	11,287	503,114

No impairments were recorded in the current or prior period.

### **Intangible Assets**

Intangible assets acquired separately, or in a business combination, are initially measured at cost. The cost of an intangible asset acquired in a business combination is its fair value as at the date of acquisition. Following initial recognition, intangible assets are carried at cost less any accumulated amortisation and any accumulated impairment losses. Internally generated intangible assets, excluding capitalised development costs, are not capitalised and expenditure is recognised in profit or loss in the year in which the expenditure is incurred.

Indefinite life intangible assets are reviewed for impairment at each reporting date, or more frequently if events or changes in circumstances indicate that the carrying value may be impaired.

Certain intangible assets other than goodwill (i.e. customer contracts, relationships, intellectual property and trademarks) have been assessed as having finite useful lives and, as such, are amortised over their useful lives. The useful lives range from five to fifteen years and are tested for impairment whenever there is an indication that the intangible asset may be impaired. The amortisation period and amortisation method for an intangible asset with a finite useful life is reviewed at least at each financial year-end. Changes in the expected useful life or the expected pattern of consumption of future economic benefits embodied in the asset are accounted for prospectively by changing the amortisation period or method, as appropriate, which is a change in an accounting estimate.

### **Significant accounting estimates and assumptions**

#### **Impairment intangible assets**

No impairments were recorded in the current or prior period.

The recoverable values of the CGUs exceed their carrying values.

An asset or a Cash Generating Unit (CGU) is considered impaired when its balance sheet carrying amount exceeds

its estimated recoverable value, which is defined as the higher of its fair value less cost of disposal and its value in use. The Group applies the value in use method which utilises net present value techniques using post-tax cash flows and discount rates.

The estimates used in calculating net present value from the value in use approach are highly sensitive, and depend on assumptions specific to the nature of the Group's activities with regard to:

- amount and timing of projected future cash flows;
- long-term sales and associated gross margin forecasts;
- sales erosion rates after the end of patent or other intellectual property rights protection and timing of entry of generic competition;
- applicable tax rates;
- behaviour of competitors (launch of competing products, marketing initiatives, etc);
- selected discount and terminal growth rates; and
- in the case of unlaunched products:
  - the outcome of R&D activities (compound efficacy, results of clinical trials, etc);
  - amount and timing of projected costs to develop in process research and development into commercially viable products; and
  - probability of obtaining regulatory approvals.

Due to the above factors, actual cash flows and values could vary significantly from forecasted future cash flows and related values derived from discounting techniques.

#### **Intangible Impairment Testing Methodology**

For impairment testing, intangible assets are allocated to individual CGUs (which are based on the product Therapeutic Groups or 'TG').

Each CGU represents the lowest level within the Group at which the asset is monitored for internal management purposes and separately identifiable cash flows are present and is not larger than a reporting segment.

The testing methodology for the recoverable value of each CGU at 31 December 2025 is as follows:

- Allocate the asset value to the relevant CGU including an allocation of corporate assets and costs;
- Estimate cash flows generated over a 5.5 year forecast period plus a terminal value calculation for the CGU (where appropriate);
- Calculate the Weighted Average Cost of Capital (WACC) of the CGU; and
- Discount the cash flows using WACC and compare to the CGU allocated asset carrying value.

Indefinite life intangible assets and intangible assets not yet available for use are included in a CGU. These include purchased assets not yet launched and development expenditure. These assets, and related cashflows, have been included in the relevant CGU for impairment testing purposes and are reviewed on at least an annual basis.

The allocation of intangible assets to CGUs as at 31 December 2025 is shown in the table below.

A\$000's	Derm	Women's Health	Infectious Disease	MPI	Total
Intangible Assets	37,594	460,243	2,572	2,705	<b>503,114</b>

The allocation of intangible assets to CGU's as at 30 June 2025 was shown in the table below:

A\$000's	Derm	Women's Health	Infectious Disease	MPI	Total
Intangible Assets	43,285	496,484	3,129	2,873	545,771

For personal use only



### Key Assumptions

Key assumptions in impairment testing methodology include:

- Cash flow forecasts for the on-market portfolio are based on FY26 forecast results as well as specific cash flows which have been forecast out to FY31. A terminal growth or erosion rate is then applied;
- Risk weighted pipeline cash flows are included in each of the relevant CGUs;
- Corporate overheads have been allocated to the relevant CGU based on their respective gross margin contributions;
- Other net assets have been allocated to the relevant CGU; and
- Individual CGU discount rates have been used.

Discount rates reflect Management's estimate of time value of money and the risks specific to the CGU and have been determined using the WACC. The pre and post-tax discount rates used are shown below (and are unchanged from 30 June 2025).

• Dermatology:	Pre-Tax – 13.3% / Post Tax – 10.2%
• Women's Health:	Pre-Tax – 13.3% / Post Tax – 10.2%
• MPI: Pre-Tax:	Pre-tax – 14.0% / Post Tax – 9.8%
• Infectious Disease:	Pre-Tax – 14.0% / Post Tax – 9.8%

Forecast gross margin growth rates by CGU are shown in the table below. These average growth rates are assumptions determined to satisfy applicable accounting standards but should not be used for guidance.

December 2025	Assumed Average Forecast Gross Margin Growth Rates <sup>(1)</sup>	Assumed Terminal Value Growth Rate
Dermatology CGU	-11.4%	0.3%
Women's Health CGU	13.2%	n/a <sup>(2)</sup>
MPI CGU	9.0%	2.0%
Infectious Disease	-8.3%	n/a <sup>(2)</sup>

Notes: (1) Growth rates refer to the Compound Annual Growth Rates (CAGR) over the forecast period and includes both on-market and pipeline assets.  
(2) For Women's Health and Infectious Disease no terminal value is included.

June 2025	Assumed Average Forecast Gross Margin Growth Rates 1st five years	Assumed Terminal Value Growth Rate
Dermatology	-16.5%	0.3% <sup>(1)</sup>
Women's Health	7.1%	n/a <sup>(2)</sup>
MPI	12.8%	2.0%
Infectious Disease	-9.8%	n/a <sup>(2)</sup>

Notes: (1) Growth rates refer to the Compound Annual Growth Rates (CAGR) over the forecast period and includes both on-market and pipeline assets. The CAGRs are calculated off the FY24 statutory result for the relevant CGU  
(2) For Women's Health and Infectious Disease no terminal value is included.

Recoverable values and carrying values are shown in the table below.

	Carrying Value <sup>(1)</sup>	Recoverable Value	Difference
Dermatology CGU	59.3	146.2	86.9
Women's Health CGU	486.1	518.2	32.1
MPI CGU	81.2	125.6	44.4
Infectious Disease CGU	2.8	6.6	3.8

Note: (1) Includes intangible assets, working capital and property, plant and equipment.

For personal use only

### Sensitivity to changes in assumptions

The tables below show the sensitivity of the changes in key variables on recoverable values for CGUs assessed on a value in use (VIU) basis.

A\$m	+/-1% Change in Gross Margin Growth	+/-1% Change in Terminal Growth Rate	+/-1% Change in WACC <sup>(1)</sup>
Dermatology CGU	+3.7/-3.8	+0.1/-0.1	0/+0.1
Women's Health CGU	+16.4/-18.9	n/a	-3.8/+4.0
MPI CGU	+1.8/-2.0	+14.8/-13.9	-10.8/+14.0
Infectious Disease CGU	+0.2/-0.2	n/a	-0.1/+0.1

Note: (1) Change refers to the movement in the post-tax WACC.

### 12. TRADE AND OTHER PAYABLES

	31 December 2025 \$'000	30 June 2025 \$'000
Trade payables	23,310	30,252
Accrued rebates, returns and loyalty programs	153,419	129,980
Other payables	13,840	14,072
	190,569	174,304

### 13. INTEREST-BEARING LOANS AND BORROWINGS

	31 December 2025 \$'000	30 June 2025 \$'000
<b>Current</b>		
Convertible notes	37,051	35,152
Lease liabilities – right-of-use assets	3,261	3,464
	40,312	38,616
<b>Non-current</b>		
Lease liabilities – right-of-use assets	2,153	2,655
	2,153	2,655

#### Convertible notes

On 31 December 2022 the Group issued convertible notes with a face value of US\$27.95m which converted to AUD on issue date (@ 0.679 A\$41.163m). The discount to face value (US\$3m) was paid by Mayne Pharma in June 2023. Key terms of these convertible notes include:

- Noteholders may redeem the notes for cash at face value upon the occurrence of certain change in control or default events or at maturity. The notes mature on 31 December 2026.
- Noteholders may convert the notes into equity at a fixed exchange rate and fixed conversion price of A\$5.356 per Mayne Pharma security (the conversion price was adjusted for certain past events including the special dividend and share consolidation which occurred in January 2023). Conversion can be exercised at any point from six months after issuance.
- Interest is payable at 2.5% per annum on the face value of A\$41.163m.

The conversion option has been assessed as an embedded derivative that is not closely related to the host convertible note liability. Accordingly, the convertible notes have been separated into two components at initial recognition as follows:

- Fair value of the conversion option (embedded derivative). This is included in “Other financial liabilities” (refer Note 14). At time of issue the derivative value was a \$9.743m liability. This embedded derivative has subsequently been accounted for at fair value.
- Loan liability representing the net proceeds received less the fair value of the conversion option. The loan liability has, after initial recognition, been accounted for at amortised cost and is classified as interest bearing loans and borrowings (as above).

#### 14. OTHER FINANCIAL LIABILITIES

	31 December 2025 \$'000	30 June 2025 \$'000
<b>Current</b>		
Earn-out liabilities and deferred consideration – various products/distribution rights	14,735	26,629
Derivative related to convertible notes	1,230	8,016
Deferred liability – MCS sale related	-	3,012
	15,965	37,657
<b>Non-current</b>		
Earn-out liabilities and deferred consideration – various products/distribution rights	321,678	371,404
	321,678	371,404

The Consolidated Entity has recognised various earn-out and deferred consideration liabilities relating to various asset purchases. Most earn-outs are based on a percentage of net sales and typically payable on a quarterly basis for a period of between two and ten years. Deferred consideration liabilities are based on sales milestones and typically payable after the end of the quarter in which the sales milestone was achieved.

At balance date the Group has assessed the amount expected to be paid for contingent amounts outlined in the asset purchase agreements, using best estimates as to timing and likelihood of payments.

The deferred liability relating to the MCS sale relates to Mayne Pharma’s commitment to contribute towards overhead recovery for the Greenville site sold to Catalent as part of the MCS sale. The agreement specifies fixed amounts payable quarterly over 3 years. The final instalments were paid during this half.

#### Significant accounting estimates and assumptions

##### *Earn-out and deferred consideration liabilities*

The earn-out liabilities are based on expected future cash flows determined as a percentage of net sales or gross margin. Deferred consideration liabilities represent the net present value of future predetermined payments. The estimation of the cash flows over a significant period, combined with the impact of currency movements and interest rates may result in substantial movements in the value of the liabilities recognised between reporting periods. The estimated cash flows, assumed discount rate and forecast exchange rates are reviewed every six months to ensure the most accurate fair value of the liabilities is reported. Movements in the liabilities from changes in these assumptions and forecasts are reported in the consolidated statement of profit or loss and other comprehensive income.

Earn-out liabilities represent the net present value of estimated future payments. After the initial recognition, any changes in fair value for changes in the net present value of estimated future payments are recognised in the

For personal use only

statement of profit or loss and other comprehensive income. The earn-out liabilities at reporting date include a charge representing the unwinding of the discounting of the earn-out liabilities of \$19,523,000 (pcp: \$17,637,000) for the period. This change arises because the present value of the of the liabilities is discounted by one less six month period. The earn-out liabilities at reporting date also include earn-out reassessments, a result of the impact on the net present value of future payments due to the Company reassessing the timing and/or value of future earn-out payments of \$54,509,000 credit to profit loss / decrease to earn-outs (pcp \$1,019,000 credit to profit loss/ decrease to earn-outs)

As at 31 December 2025 the deferred consideration amounts consist mainly of fixed amounts which are subject to sales milestone requirements.

*Derivative related to convertible notes*

Convertible notes have been separated into two liabilities – the fair value of the loan liability recorded at amortised cost and is classified as interest bearing loans and borrowings and the fair value of the conversion option (embedded derivative) which is included above in “Other financial liabilities”.

**15. PROVISIONS**

	31 December 2025 \$'000	30 June 2025 \$'000
<b>Current</b>		
Employee entitlements	10,538	10,434
	<b>10,538</b>	<b>10,434</b>
<b>Non-current</b>		
Employee entitlements	477	457
	<b>477</b>	<b>457</b>

**16. CONTRIBUTED EQUITY**

**(a) Issued capital**

	31 December 2025 \$'000	30 June 2025 \$'000
Ordinary shares, fully paid	1,229,773	1,225,979

**(b) Movements in share capital**

	Number	\$'000
Balance at beginning of period	81,245,827	1,225,979
Conversion of employee LTI awards	-	3,794
<b>Balance at end of period</b>	<b>81,245,827</b>	<b>1,229,773</b>

**17. DIVIDENDS**

No dividend has paid or declared in the current or prior period.

For personal use only



## 18. COMMITMENTS AND CONTINGENCIES

### A. Capital Commitments

The Group had \$0.9m of contractual obligations for the purchase of capital equipment relating to the Salisbury site as at 31 December 2025.

### B. Contingencies

Some Mayne Pharma companies are, or will likely in the future, be subject to various legal proceedings and investigations that arise from time to time. These may include proceedings regarding product liability and personal injury, sales and marketing practices, continuous disclosure obligations, commercial disputes or antitrust and intellectual property matters. As a result, the Group may become subject to substantial liabilities that may not be covered by insurance and that could affect our business, financial position and reputation. Litigation is inherently unpredictable and large judgements sometimes occur. Consequently, Mayne Pharma may in the future incur judgements or enter into settlements of claims that could have a material adverse effect on its operating results and/or cash flow.

Mayne Pharma has not made provisions for potential damage or other remedies for legal claims against it or its subsidiaries where Mayne Pharma currently believes that a payment is either not probable or cannot be reliably estimated.

Summary of significant investigations and legal proceedings currently brought against the Company seeking damages or other remedies

The legal claims and allegations summarised below are being vigorously contested. In relation to matters no payment is considered probable and possible related amounts cannot be reliably estimated and as such no amounts have been provided at reporting date.

#### *Drug pricing matters - litigation*

In the last few years, Mayne Pharma Inc has been sued alongside other generic pharmaceutical companies in civil complaints alleging anticompetitive conduct in the sale of generic drugs with claims related to drugs sold by Mayne Pharma as well as allegations that all defendants were part of an overarching, industry wide conspiracy to allocate markets and fix prices generally. The civil complaints include a complaint by the attorneys general of 45 US states, the District of Columbia and the Commonwealth of Puerto Rico, and class action lawsuits filed by direct purchasers (including one in Canada), end-payors, and indirect resellers, as well as lawsuits filed by opt out private plaintiffs and various county plaintiffs. Nearly all of the private US cases have been consolidated into multidistrict litigation pending in federal court, the Eastern District of Pennsylvania; the state action (brought by the state attorneys general) has been remanded to the District of Connecticut. One opt-out action is pending in state court in New York, and three writs of action are in deferred status in state court in Pennsylvania. Mayne Pharma is strongly defending the allegations made in these civil complaints.

#### *Federal Health care – investigation*

In July 2021, the Company received a Civil Investigative Demand (CID) from the Civil Division of the US Department of Justice (DOJ) seeking information relating to claims submitted to federal health care programs and surrounding select branded products. Mayne Pharma is fully cooperating with this investigation.

In April 2023, the Company received subpoenas from the California Department of Insurance seeking information similar to that contained in the DOJ's above-referenced CID. Mayne Pharma is fully cooperating with this investigation.

*TherapeuticsMD, Inc. and Mayne Pharma LLC v. Teva Pharmaceuticals USA, Inc.*, Civil Action Nos. 2:20-cv-03485-BRM-SDA; 2:20-cv-08809-BRM-ESK; 2:20-cv-11087-BRM-ESK; 2:20-cv-17496-BRM-ESK; 2:21-cv-12794-BRM-SDA; 2:24-cv-11161-BRM-SDA (D.N.J.)

TherapeuticsMD, Inc. received a Paragraph IV Notice Letter from generic drug maker Teva Pharmaceuticals USA, Inc. ("Teva") dated February 18, 2020 directed to five of its Imvexy® Orange Book patents. TherapeuticsMD, Inc.'s U.S. Patent Nos. 9,180,091; 9,289,382; 10,258,630; 10,398,708; and 10,471,072 generally cover vaginal estradiol

formulations and methods of treating certain conditions using those formulations. FDA's Orange Book lists November 21, 2032 as the expiration date of U.S. Patent No. 9,180,091; U.S. Patent No. 9,289,382; U.S. Patent No. 10,258,630; U.S. Patent No. 10,398,708 ; and U.S. Patent No. 10,471,072. On April 1, 2020, TherapeuticsMD, Inc. filed a lawsuit against Teva alleging infringement of TherapeuticsMD, Inc.'s five patents. The Complaint—filed in the U.S. District Court for the District of New Jersey—alleges, inter alia, that Teva infringed TherapeuticsMD, Inc.'s Imvexxy® patents by submitting to FDA an Abbreviated New Drug Application (“ANDA”) seeking to market a generic version of Imvexxy® prior to the expiration of TherapeuticsMD, Inc.'s patents. Filing its April 1, 2020 Complaint within 45 days of receiving Teva's Paragraph IV certification notice entitles TherapeuticsMD, Inc. to an automatic stay preventing FDA from approving Teva's ANDA for 30 months from the date of TherapeuticsMD, Inc.'s receipt of the Paragraph IV Notice Letter. Teva filed an Answer and Amended Answer on June 15, 2020 and July 2, 2020, respectively, denying the substantive allegations of the Complaint and asserting Counterclaims seeking declaratory judgments of non-infringement and invalidity. On July 13, 2020, TherapeuticsMD, Inc. filed its Reply, denying the substantive allegations of Teva's Counterclaims.

TherapeuticsMD, Inc. received a Paragraph IV Notice Letter from Teva dated June 2, 2020 directed to TherapeuticsMD, Inc.'s U.S. Patent Nos. 10,537,581 and 10,568,891, which generally cover vaginal estradiol formulations and methods of treating certain conditions using those formulations. FDA's Orange Book states that U.S. Patent Nos. 10,537,581 and 10,568,891 expire on November 21, 2032. On July 13, 2020, TherapeuticsMD, Inc. filed a lawsuit against Teva alleging infringement of TherapeuticsMD, Inc.'s U.S. Patent Nos. 10,537,581 and 10,568,891. The Complaint—filed in the U.S. District Court for the District of New Jersey—alleges, inter alia, that Teva infringed TherapeuticsMD, Inc.'s Imvexxy® patents by submitting to FDA an ANDA seeking to market a generic version of Imvexxy® prior to the expiration of TherapeuticsMD, Inc.'s patents. On August 5, 2020, Teva answered the Complaint and denied the substantive allegations of the Complaint. Teva also asserted Counterclaims seeking declaratory judgments of non-infringement and invalidity. On August 19, 2020, TherapeuticsMD, Inc. filed its Reply, denying the substantive allegations of Teva's Counterclaims. On August 14, 2020, the Court issued an Order consolidating Civil Action Nos. 20-3485 and 20-8809 for all purposes.

TherapeuticsMD, Inc. received a Paragraph IV Notice Letter from Teva dated August 5, 2020 directed to TherapeuticsMD, Inc.'s U.S. Patent No. 10,668,082, which generally covers vaginal estradiol formulations and methods of treating certain conditions using those formulations. FDA's Orange Book states that U.S. Patent No. 10,668,082 expires on November 21, 2032. On August 21, 2020, TherapeuticsMD, Inc. filed a lawsuit against Teva alleging infringement of TherapeuticsMD, Inc.'s U.S. Patent No. 10,668,082. The Complaint—filed in the U.S. District Court for the District of New Jersey—alleges, inter alia, that Teva infringed TherapeuticsMD, Inc.'s Imvexxy® patent by submitting to FDA an ANDA seeking to market a generic version of Imvexxy® prior to the expiration of TherapeuticsMD, Inc.'s patent. On September 9, 2020, Teva answered the Complaint and denied the substantive allegations of the Complaint. Teva also asserted Counterclaims seeking declaratory judgments of non-infringement and invalidity. On September 23, 2020, TherapeuticsMD, Inc. filed its Reply, denying the substantive allegations of Teva's Counterclaims. On September 18, 2020, the Court issued an Order consolidating Civil Action Nos. 20-3485 and 20 11087 for all purposes.

TherapeuticsMD, Inc. received a Paragraph IV Notice Letter from Teva dated February 4, 2021 directed to TherapeuticsMD, Inc.'s U.S. Patent Nos. 10,806,697 and 10,835,487, which generally cover vaginal estradiol formulations and methods of treating certain conditions using those formulations. FDA's Orange Book states that U.S. Patent Nos. 10,806,697 and 10,835,487 expire on November 21, 2032. Prior to receiving Teva's notice letter, on November 30, 2020, TherapeuticsMD, Inc. filed a lawsuit against Teva alleging infringement of TherapeuticsMD, Inc.'s U.S. Patent Nos. 10,806,697 and 10,835,487. The Complaint—filed in the U.S. District Court for the District of New Jersey—alleges, inter alia, that Teva infringed TherapeuticsMD, Inc.'s Imvexxy® patents by submitting to FDA an ANDA seeking to market a generic version of Imvexxy® prior to the expiration of TherapeuticsMD, Inc.'s patents. On December 21, 2020, Teva answered the Complaint and denied the substantive allegations of the Complaint. Teva also asserted Counterclaims seeking declaratory judgments of non-infringement and invalidity. On January 11, 2021, TherapeuticsMD, Inc. filed its Reply, denying the substantive allegations of Teva's Counterclaims. On December 9, 2020, the Court issued an Order consolidating Civil Action Nos. 20-3485 and 20 17496 for all purposes.

TherapeuticsMD, Inc. received a Paragraph IV Notice Letter from Teva dated May 13, 2021 directed to TherapeuticsMD, Inc.'s U.S. Patent No. 10,888,516, which generally covers vaginal estradiol formulations and methods of treating certain conditions using those formulations. FDA's Orange Book states that U.S. Patent No. 10,888,516 expires on November 21, 2032. On June 21, 2021, TherapeuticsMD, Inc. filed a lawsuit against Teva alleging infringement of TherapeuticsMD, Inc.'s U.S. Patent No. 10,888,516. The Complaint—filed in the U.S. District Court for the District of New Jersey—alleges, inter alia, that Teva infringed TherapeuticsMD, Inc.'s Imvexxy® patent by submitting to FDA an ANDA seeking to market a generic version of Imvexxy® prior to the expiration of TherapeuticsMD, Inc.'s patent.

For personal use only



On July 27, 2021, the Court issued an Order staying all of the above-captioned litigation and extending the 30-month stay for a number of days equal to the number of days the litigation stay is in place.

On July 13, 2023, the Court issued an Order amending the caption in the above-captioned litigation to add Mayne Pharma LLC as a plaintiff, and reinstating the litigation stay. On November 20, 2024, the Court issued an Order lifting the stay.

TherapeuticsMD, Inc. and Mayne Pharma LLC received a Paragraph IV Notice Letter from Teva dated November 13, 2024 directed to nine of the Imvexxy® Orange Book patents. U.S. Patent Nos. 11,065,197; 11,123,283; 11,116,717; 11,304,959; 11,241,445; 11,266,661; 11,246,875; 11,351,182; and 11,497,709 generally cover vaginal estradiol formulations and methods of treating certain conditions using those formulations. FDA's Orange Book states that U.S. Patent Nos. 11,065,197; 11,123,283; 11,116,717; 11,304,959; 11,241,445; 11,246,875; 11,351,182; and 11,497,709 expire on November 21, 2032; and U.S. Patent No. 11,266,661 expires on February 2, 2034. On December 13, 2024, TherapeuticsMD, Inc. and Mayne Pharma LLC filed a lawsuit against Teva alleging infringement of TherapeuticsMD, Inc.'s U.S. Patent Nos. 11,065,197; 11,123,283; 11,116,717; 11,304,959; 11,241,445; 11,266,661; 11,246,875; 11,351,182; and 11,497,709. The Complaint—filed in the U.S. District Court for the District of New Jersey—alleges, inter alia, that Teva infringed TherapeuticsMD, Inc.'s Imvexxy® patents by submitting to FDA an ANDA seeking to market a generic version of Imvexxy® prior to the expiration of TherapeuticsMD, Inc.'s patents.

On December 23, 2024, the Court issued an Order consolidating Civil Action Nos. 20-3485, 21-12794, and 24-11161 for all purposes. On January 7, 2025, Teva Answered the Complaints in Civil Action Nos. 21-12794 and 24-11161 and denied the substantive allegations of the Complaints. Teva also asserted Counterclaims seeking declaratory judgments of non-infringement and invalidity. On January 28, 2025, Plaintiffs filed their Reply, denying the substantive allegations of Teva's Counterclaims. On October 6, 2025, the Court ordered that Civil Action Nos. 20-3485 and 24-7974 (see below) are consolidated under Civil Action No. 20-3485 for the purposes of discovery, case management, and trial, subject to further order of the Court. On January 30, 2026, the Court Ordered a Stipulation in which, among other things, Teva stipulated that Teva's submission of its ANDA to FDA and any commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of Teva's ANDA Product infringes certain claims of the Imvexxy® Orange Book patents provided that: (i) Plaintiff presents the claim(s) at trial against Teva; and (ii) the claim(s) are not found to be invalid or unenforceable at trial. Pretrial discovery is ongoing in these consolidated cases.

*TherapeuticsMD, Inc. and Mayne Pharma LLC v. Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries, Inc.*, Civil Action No. 2:24-cv-07974-BRM-SDA (D.N.J.)

TherapeuticsMD, Inc. and Mayne Pharma LLC received a Paragraph IV Notice Letter from generic drug maker Sun Pharmaceutical Industries Ltd. dated June 14, 2024 directed to twenty of the Imvexxy® Orange Book patents. TherapeuticsMD, Inc.'s U.S. Patent Nos. 9,180,091; 9,289,382; 10,258,630; 10,398,708; 10,471,072; 10,537,581; 10,568,891; 10,668,082; 10,806,697; 10,835,487; 10,888,516; 11,065,197; 11,116,717; 11,123,283; 11,241,445; 11,246,875; 11,266,661; 11,304,959; 11,351,182; and 11,497,709 generally cover vaginal estradiol formulations and methods of treating certain conditions using those formulations. FDA's Orange Book lists November 21, 2032 as the expiration date of U.S. Patent Nos. 9,180,091; 9,289,382; 10,258,630; 10,398,708; 10,471,072; 10,537,581; 10,568,891; 10,668,082; 10,806,697; 10,835,487; 10,888,516; 11,065,197; 11,116,717; 11,123,283; 11,241,445; 11,246,875; 11,304,959; 11,351,182; and 11,497,709. FDA's Orange Book lists February 2, 2034 as the expiration date of U.S. Patent No. 11,266,661. On July 24, 2024, TherapeuticsMD, Inc. and Mayne Pharma LLC filed a lawsuit against Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries, Inc. (collectively, "Sun"), alleging infringement of the Imvexxy® Orange Book patents. The Complaint—filed in the U.S. District Court for the District of New Jersey—alleges, inter alia, that Sun infringed the Imvexxy® patents by submitting to FDA an ANDA seeking to market a generic version of Imvexxy® prior to the expiration of the Imvexxy Orange Book patents. Filing the July 24, 2024 Complaint within 45 days of receiving Sun Pharmaceutical Industries Ltd.'s Paragraph IV certification notice entitles TherapeuticsMD, Inc. and Mayne Pharma LLC to an automatic stay preventing FDA from approving Sun's ANDA for 30 months from the date of TherapeuticsMD, Inc.'s and Mayne Pharma LLC's receipt of the Paragraph IV Notice Letter. On September 30, 2024, Sun Answered the Plaintiffs' Complaint and denied the substantive allegations of the Complaint. Sun also asserted Counterclaims seeking declaratory judgments of non-infringement and invalidity. On November 4, 2024, Plaintiffs filed their Reply, denying the substantive allegations of Sun's Counterclaims. On October 6, 2025, the Court ordered that Civil Action Nos. 20-3485 and 24-7974 are consolidated under Civil Action No. 20-3485 (see above) for the purposes of discovery, case management, and trial, subject to further order of the Court. On December 9, 2025, the Court Ordered a Stipulation in which, among other things, Sun stipulated that Sun's submission of its ANDA to FDA and any commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of Sun's ANDA Product infringes certain

For personal use only

claims of the Imvexxy® Orange Book patents provided that: (i) Plaintiff presents the claim(s) at trial against Sun; and (ii) there is no final court decision finding the claim(s) presented at trial against Sun invalid or unenforceable. Pretrial discovery is ongoing in consolidated Civil Action No. 20-3485 (see above).

#### *Dispute with Cosette*

On 15 October 2025, the Supreme Court of New Wales delivered reasons determining the proceedings commenced by Mayne Pharma against Cosette in Mayne Pharma's favour.

On 16 October 2025, the Supreme Court of New South Wales made orders, including orders that Cosette had not validly terminated the SID, dismissing Cosette's cross-claim against Mayne Pharma and ordering that Cosette pay Mayne Pharma's costs of the proceedings as agreed or assessed.

On 10 November 2025, Cosette served Mayne Pharma with a Notice of Intention to Appeal, notifying Mayne Pharma of an intention to appeal the decision of Justice Black in the Supreme Court of New South Wales.

On 15 January 2026, Cosette served Mayne Pharma with a Notice of Appeal, appealing the decision of Justice Black in the Supreme Court of New South Wales, Court of Appeal.

On 11 February 2026, Mayne Pharma served Cosette with a Notice of Contention, notifying Cosette that it was seeking to affirm the decision of Justice Black on grounds other than those relied on by his Honour to determine the proceeding.

On 18 February 2026, Mayne Pharma commenced proceedings in the Supreme Court of New South Wales against Cosette Pharmaceuticals, Inc, Cosette Pharmaceuticals Holdings, Inc, Avista Capital Holdings, LP trading as Avista Healthcare Partners (Avista) and David Burgstahler (the Managing Partner and CEO of Avista) seeking substantial damages on behalf of Mayne Pharma shareholders against Cosette for breach of the Scheme Implementation Deed (SID) and against the other defendants for inducing Cosette's breach of the SID. Mayne Pharma is also seeking substantial damages on its own behalf against the defendants.

On 18 February 2026, the Court of Appeal listed the appeal for a 2-day hearing on 2 and 3 June 2026.

Mayne Pharma is seeking an order from the Court that Cosette provide Mayne Pharma with security for its costs associated with the appeal.

Mayne Pharma is also taking steps to enforce the costs order made against Cosette in Supreme Court of New South Wales proceeding.

#### *Dispute with TXMD*

In April 2025, TherapeuticsMD, Inc. (TXMD) filed a suit against Mayne Pharma LLC making allegations against Mayne Pharma related to the transaction agreement entered into between TXMD and Mayne Pharma LLC on 4 December 2022. This proceeding is not an attempt to terminate the transaction agreement or the license agreement entered into between TXMD and Mayne Pharma LLC on 4 December 2022, or Mayne Pharma's rights with respect to the products licensed from TXMD.

In June 2025, Mayne Pharma filed a complaint against TXMD alleging damages which Mayne Pharma believes are in excess of the value of the claims made by TXMD. The various claims in these proceedings brought by each of TXMD and Mayne Pharma are related to a series of disputes that have been in discussion between Mayne Pharma and TXMD for some time. Mayne Pharma intends to vigorously defend the proceeding brought by TXMD.

#### *Additional Matters*

On 6 February 2026, Mayne Pharma was served with a personal injury claim in relation to the use of a generic product formerly commercialised by Mayne Pharma in the US. Mayne Pharma is currently evaluating the claim and intends to vigorously defend the allegations made in the complaint.

## 19. FINANCIAL INSTRUMENTS

Set out below is an overview of financial instruments, other than cash and short-term deposits, held by the Group as at 31 December 2025.

	31 December 2025 \$'000	30 June 2025 \$'000
<b>Financial liabilities</b>		
<b>Current</b>		
Earn-out and deferred consideration liabilities	14,735	26,629
Embedded derivative convertible notes	1,230	8,016
	15,965	34,645
<b>Non-current</b>		
Earn-out and deferred consideration liabilities	321,678	371,404
	321,678	371,404

Trade and other receivables, trade and other payables, other financial assets and other liabilities are considered short term and their fair values approximates the carrying values.

### Fair Value

Set out below is a comparison by class of the carrying amounts and fair value of the Group's financial instruments that are carried in the financial statements.

	Carrying Amount		Fair Value	
	31 Dec 2025 \$'000	30 June 2025 \$'000	31 Dec 2025 \$'000	30 June 2025 \$'000
<b>Liabilities</b>				
Earn-out and deferred consideration liabilities	336,413	401,045	336,413	401,045
Embedded derivative convertible notes	1,230	8,016	1,230	8,016

### Derivative related to convertible notes

The conversion option of the convertible notes has been assessed as an embedded derivative that is not closely related to the host convertible note liability. Accordingly, the convertible notes have been separated into two components at initial recognition as follows:

Fair value of the conversion option (embedded derivative). This is included in "Other financial liabilities" (refer Note 14). At time of issue this derivative was a \$9.743m liability. The subsequent fair value changes in the embedded derivative have been accounted for through profit and loss.

Loan liability represents the net proceeds received less the fair value of the conversion option. The loan liability is subsequently accounted for at amortised cost and is classified as interest bearing loans and borrowings (refer Note 13).

The value of the derivative has been determined using a Black-Scholes model. Significant inputs to the model utilised at 31 December 2025 are Mayne Pharma's:

- Stock price, \$3.11
- Conversion price \$5.356
- Expected volatility 50%
- Estimated credit spread 5.5%.

The value derived is considered Level 3 in the fair value hierarchy.

The Consolidated Entity has recognised various earn-out liabilities relating to various asset purchases. Most earn-outs are based on a percentage of net sales or gross margin and typically payable on a quarterly basis for a period

of between two and ten years.

At balance date the Group has assessed the amount expected to be paid for contingent amounts outlined in the asset purchase agreements, using best estimates as to timing and likelihood of payments.

At balance date the deferred consideration amounts consist mainly of fixed amounts which are subject to sales milestone requirements.

Set out below are the significant unobservable inputs to valuation as at 31 December 2025:

Earn-out / deferred consideration	Valuation technique	Significant unobservable inputs	Input used	Sensitivity of the input to fair value
NEXTSTELLIS® – deferred consideration liability	DCF	Forecast net sales  WACC	10.2%	5% increase (decrease) in net sales would change the expected timing of milestone payments resulting in an increase (decrease) in fair value by \$10.4m / (\$2.2m). 1% increase / (decrease) in the WACC would result in decrease / (increase) in fair value by \$5.9m / (\$6.3m).
TXMD earn-out and deferred consideration liability	DCF	Forecast net sales  WACC	10.2%	5% increase (decrease) in net sales would change the expected timing of milestone payments resulting in an increase (decrease) in fair value by \$10.0m / (\$8.8m). 1% increase / (decrease) in the WACC would result in decrease / (increase) in fair value by \$12.0m / (\$13.1m).

**Fair value hierarchy**

The Group uses the following hierarchy for determining and disclosing the fair value of financial instruments by valuation technique:

- Level 1: Quoted (unadjusted) market prices in active markets for identical assets or liabilities.
- Level 2: Valuation techniques for which the lowest level input that is significant to the fair value measurement is directly or indirectly observable.
- Level 3: Valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable.

**Assets and liabilities measured at fair value**

As at 31 December 2025, the Group held the following financial instruments carried at fair value in the Statement of Financial Position:

	Level 2		Level 3	
	31 December 2025 \$'000	30 June 2025 \$'000	31 December 2025 \$'000	30 June 2025 \$'000
<b>Financial Liabilities</b>				
Earn-out and deferred consideration liabilities	-	-	336,413	401,045
Embedded derivative convertible notes	-	-	1,230	8,016

For personal use only

### Reconciliation of fair value measurements of Level 3 financial instruments

The Group carries earn-out and deferred consideration liabilities classified as Level 3 within the fair value hierarchy.

A reconciliation of the beginning and closing balances including movements is summarised below:

	<b>Dec 2025 Earn-out &amp; deferred consideration liabilities \$'000</b>
Opening balance 1 July 2025	401,045
Discount unwind	19,523
Reassessments	(54,509)
Foreign currency restatement	(8,980)
Payments	(20,666)
Closing Balance 31 December 2025	<b>336,413</b>

During the six-month period ended 31 December 2025, there were no transfers between Level 1 and Level 2 fair value measurements. The fair value increments and decrements were recorded in determining profit before tax.

### 20. EVENTS SUBSEQUENT TO REPORTING DATE

On 15 January 2026, Cosette filed an appeal against Justice Black's decision in the Supreme Court of New South Wales, Court of Appeal. The appeal has been listed for a 2-day hearing on 2 and 3 June 2026.

On 18 February 2026, Mayne Pharma commenced proceedings in the Supreme Court of New South Wales against Cosette Pharmaceuticals, Inc, Cosette Pharmaceuticals Holdings, Inc, Avista Capital Holdings, LP trading as Avista Healthcare Partners (Avista) and David Burgstahler (the Managing Partner and CEO of Avista) seeking substantial damages on behalf of Mayne Pharma shareholders against Cosette for breach of the Scheme Implementation Deed (SID) and against the other defendants for inducing Cosette's breach of the SID. Mayne Pharma is also seeking substantial damages on its own behalf against the defendants.

Mr Shawn Patrick O'Brien stepped down as Chief Executive Officer and Managing Director effective 20 February 2026 (US time) and Mr Aaron Gray (previously Mayne Pharma's Chief Financial Officer) was appointed Chief Executive Officer as part of Mayne Pharma's planned leadership transition. Refer Mayne Pharma's ASX announcement dated 23 February 2026.

No other matter or circumstance has arisen since the reporting date which is not otherwise reflected in this report that significantly affected or may significantly affect the operations of the Consolidated Entity.



## DIRECTORS' DECLARATION

In accordance with a resolution of the directors of Mayne Pharma Group Limited, we state that:

In the opinion of the directors:

- (a) the financial statements and notes of the Consolidated Entity are in accordance with the *Corporations Act 2001*, including:
  - (i) giving a true and fair view of the financial position as at 31 December 2025 and the performance for the half-year ended on that date of the Consolidated Entity; and
  - (ii) complying with Accounting Standard AASB 134 *Interim Financial Reporting* and Corporations Regulations 2001;
- (b) there are reasonable grounds to believe that the Company will be able to pay its debts as and when they become due and payable.

On behalf of the Board

A handwritten signature in black ink, appearing to read "B. Robinson", written over a light yellow rectangular background.

**Bruce Robinson, AC**  
Independent Chair

Melbourne, 23 February 2026



## AUDITOR'S INDEPENDENT REVIEW REPORT



Tel: +61 3 9603 1700  
Fax: +61 3 9602 3870  
www.bdo.com.au

Collins Place  
Level 25, 35 Collins Street  
Melbourne VIC 3000  
GPO Box 5099 Melbourne VIC 3001  
Australia

### INDEPENDENT AUDITOR'S REVIEW REPORT

To the members of Mayne Pharma Group Limited

#### Report on the Half-Year Financial Report

##### Conclusion

We have reviewed the half-year financial report of Mayne Pharma Group Limited (the Company) and its subsidiaries (the Group), which comprises the consolidated statement of financial position as at 31 December 2025, the consolidated statement of profit or loss and other comprehensive income, the consolidated statement of changes in equity and the consolidated statement of cash flows for the half-year ended on that date, material accounting policy information and other explanatory information, and the directors' declaration.

Based on our review, which is not an audit, we have not become aware of any matter that makes us believe that the accompanying half-year financial report of the Group does not comply with the *Corporations Act 2001* including:

- i. Giving a true and fair view of the Group's financial position as at 31 December 2025 and of its financial performance for the half-year ended on that date; and
- ii. Complying with Accounting Standard AASB 134 *Interim Financial Reporting and the Corporations Regulations 2001*.

##### Basis for conclusion

We conducted our review in accordance with ASRE 2410 *Review of a Financial Report Performed by the Independent Auditor of the Entity*. Our responsibilities are further described in the *Auditor's Responsibilities for the Review of the Financial Report* section of our report. We are independent of the Group in accordance with the auditor independence requirements of the *Corporations Act 2001* and the ethical requirements of the Accounting Professional and Ethical Standards Board's APES 110 *Code of Ethics for Professional Accountants (including Independence Standards)* (the Code) that are relevant to the audit of the annual financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

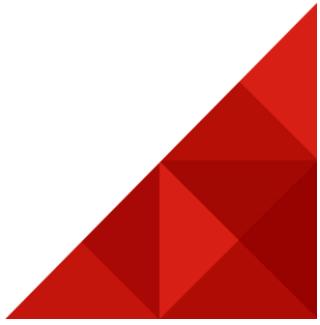
We confirm that the independence declaration required by the *Corporations Act 2001* which has been given to the directors of the Company, would be the same terms if given to the directors as at the time of this auditor's review report.

##### Responsibility of the directors for the financial report

The directors of the Company are responsible for the preparation of the half-year financial report that gives a true and fair view in accordance with Australian Accounting Standards and the *Corporations Act 2001* and for such internal control as the directors determine is necessary to enable the preparation of the half-year financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error.

BDO Audit Pty Ltd ABN 33 134 022 870 is a member of a national association of independent entities which are all members of BDO International Ltd, a UK company limited by guarantee, and form part of the international BDO network of independent member firms. Liability limited by a scheme approved under Professional Standards Legislation.

For personal use only





**Auditor's responsibility for the review of the financial report**

Our responsibility is to express a conclusion on the half-year financial report based on our review. ASRE 2410 requires us to conclude whether we have become aware of any matter that makes us believe that the half-year financial report is not in accordance with the *Corporations Act 2001* including giving a true and fair view of the Group's financial position as at 31 December 2025 and its financial performance for the half-year ended on that date and complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*.

A review of a half-year financial report consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

BDO Audit Pty Ltd

A stylized signature of Benjamin Lee in black ink.A handwritten signature in black ink, likely of Benjamin Lee.

Benjamin Lee  
Director

Melbourne, 23 February 2026

For personal use only



## INTELLECTUAL PROPERTY & GLOSSARY

RHOFADE® is a trademark of the Consolidated Entity. ANNOVERA®, BIJUVA®, EPSOLAY®, IMVEXXY®, KADIAN®, NEXTSTELLIS®, ORACEA® and TWYNEO® are trademarks of third parties.

For further information on Mayne Pharma's products, refer to the product section of the Company's website, <http://www.maynepharma.com/products/us-products/> or <http://www.maynepharma.com/products/australian-products/>.

## GLOSSARY

ANDA – Abbreviated New Drug Application. An application to market a generic drug in the US. Generic drug applications are called "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness. Instead, a generic applicant must scientifically demonstrate that its product is bioequivalent (i.e., performs in the same manner as the innovator drug). Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, low-cost alternative to the American public.

API - Active Pharmaceutical Ingredient. An active ingredient is any component that provides pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or animals.

FDA – US Food and Drug Administration. The US FDA is responsible for protecting public health by assuring the safety, efficacy and security of, amongst other things, human drugs.

NDA - New Drug Application. When the sponsor of a new drug believes that enough evidence on the drug's safety and effectiveness has been obtained to meet FDA's requirements for marketing approval, the sponsor submits to FDA a new drug application (NDA). The application must contain data from specific technical viewpoints for review, including chemistry, pharmacology, medical, biopharmaceutics, and statistics. If the NDA is approved, the product may be marketed in the United States.

OTC - Over-the-Counter pharmaceuticals. Products that are considered safe and effective by the FDA and TGA for use by the general public without a doctor's prescription.

PIV - Paragraph IV filing. A type of filing to support the approval of an ANDA submitted while the originator product is covered by a patent. The filing asserts that either the patents supporting the originator product are invalid or that they are not applicable to the product that is the subject of the ANDA.

TGA – Therapeutic Goods Administration. The TGA is Australia's regulatory authority for therapeutic goods.

