

23 August 2019

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

Via E-Lodgement

Dear Sir/Madam

**Mayne Pharma Group Limited
Preliminary Final Report and accompanying announcement**

Please find attached the following documents relating to the results for the year ended 30 June 2019.

- Appendix 4E
- Annual Financial Statements

This announcement comprises the information required by ASX Listing Rule 4.3A.

Yours faithfully,
Mayne Pharma Group Limited



Nick Freeman
Group CFO and Company Secretary



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RESULTS FOR ANNOUNCEMENT TO THE MARKET

APPENDIX 4E – PRELIMINARY FINAL REPORT

	% CHANGE	30 JUNE 2019 \$'000	30 JUNE 2018 \$'000
Revenue from ordinary activities	(1%)	525,208	530,313
Profit / (loss) from ordinary activities before income tax expense	(112%)	(353,717)	(166,787)
Profit / (loss) from ordinary activities after income tax expense		(283,751)	(134,257)
Attributable to:			
Equity holders of the parent	(110%)	(280,866)	(133,984)
Non-controlling interests		(2,885)	(273)
	(111%)	(283,751)	(134,257)
Other comprehensive profit/(loss) after income tax expense		46,013	41,999
Total comprehensive income for the period	(158%)	(237,738)	(92,258)
Attributable to:			
Equity holders of the parent	(155%)	(235,354)	(92,365)
Non-controlling interests		(2,384)	107
		(237,738)	(92,258)
Net tangible assets per ordinary share		\$0.15	\$0.12
		2019 Cents	2018 Cents
Basic earnings per share		(19.04)	(9.16)
Diluted earnings per share		(19.04)	(9.16)
Final dividend in respect of the financial year ended 30 June per share		Nil	Nil

No dividend has been declared in relation to the period ended 30 June 2019.

Refer to the Review of Operations and Likely Developments and the accompanying ASX announcement dated 23 August 2019 for a brief commentary on the results.

Financial Report 2019

MAYNE PHARMA GROUP LIMITED

ABN 76 115 832 963

FOR THE YEAR ENDED 30 JUNE 2019
(PRIOR CORRESPONDING PERIOD: YEAR ENDED 30 JUNE 2018)



maynepharma

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DIRECTORS' REPORT

The Directors of Mayne Pharma Group Limited ('the Company') present their report together with the financial report of the Company and its controlled entities (collectively the 'Group' or 'Consolidated Entity' or 'Mayne Pharma') for the year ended 30 June 2019 and the Auditor's Report thereon. The information set out below is to be read in conjunction with the Remuneration Report set out on pages 15 to 21, which forms part of this Directors' Report.

DIRECTORS

The Directors of the Company during the financial year and up to the date of this report are:

Mr Roger Corbett, AO (Chairman)
Mr Scott Richards (Managing Director and Chief Executive Officer)
Hon Ron Best
Mr Patrick Blake
Mr Frank Condella
Ms Nancy Dolan
Mr William (Phil) Hodges (resigned 29 November 2018)
Mr Bruce Mathieson
Prof Bruce Robinson, AM
Mr Ian Scholes

The Directors' qualifications, other listed company directorships, experience and special responsibilities are detailed on pages 10 and 11 of this report. The qualifications and experience of the Company Secretary are detailed on page 11 of this report.

DIRECTORS' MEETINGS

The number of Directors' meetings (including meetings of committees of Directors) and number of meetings attended by each of the Directors of the Company during the 2019 financial year are:

	BOARD		AUDIT & RISK COMMITTEE		NOMINATION COMMITTEE		REMUNERATION & PEOPLE COMMITTEE		SCIENCE, TECHNOLOGY & MEDICAL COMMITTEE	
	HELD ¹	ATTENDED ²	HELD ¹	ATTENDED ²	HELD ¹	ATTENDED ²	HELD ¹	ATTENDED ²	HELD ¹	ATTENDED ²
Mr R Corbett	13	13	-	-	-	-	5	5	-	-
Mr S Richards ^{3,4}	13	13	-	-	-	-	5	5	3	3
Mr P Blake	13	13	-	-	-	-	-	-	-	-
Hon R Best	13	13	6	6	-	-	5	5	-	-
Mr F Condella	13	13	-	-	-	-	-	-	2	2
Ms N Dolan	13	13	6	6	-	-	-	-	-	-
Mr P Hodges	6	6	-	-	-	-	-	-	3	2
Mr B Mathieson	13	10	-	-	-	-	-	-	-	-
Prof Bruce Robinson	13	13	-	-	-	-	-	-	4	4
Mr I Scholes	13	13	6	6	-	-	5	5	-	-

1. This column shows the number of meetings held during the period the Director was a member of the Board or Committee.
2. This column shows the number of meetings attended.
3. Mr Richards is not a member of the Remuneration and People Committee however he attends meetings at the Chairman's invitation.
4. Mr Richards is not a member of the Science, Technology & Medical Committee however he attends meetings at the Chairman's invitation.

SIGNIFICANT CHANGES IN THE STATE OF AFFAIRS

These changes are discussed in the Principal Activities and Review of Operations and Likely Developments sections of this report.

PRINCIPAL ACTIVITIES

Mayne Pharma is an ASX-listed specialty pharmaceutical company focused on applying its drug delivery expertise to commercialise branded and generic pharmaceuticals. Mayne Pharma also provides contract development and manufacturing services to more than 100 clients worldwide.

Mayne Pharma has a 30-year track record of innovation and success in developing new oral drug delivery systems and these technologies have been successfully commercialised in numerous products that have been marketed around the world.

Mayne Pharma has two product development and manufacturing facilities based in Salisbury, South Australia and Greenville, North Carolina US with expertise in the formulation of complex oral and topical dose forms including potent compounds, controlled substances, modified release products and inherently unstable compounds.

REVIEW OF OPERATIONS AND LIKELY DEVELOPMENTS

Summary of financial performance

Set out below is a summary of the financial performance attributable to Mayne Pharma shareholders for the 2019 financial year (FY19) compared to the prior corresponding period (pcp).

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, depreciation and amortisation ('EBITDA') is used as a key measure of the earnings considered by management in operating the business and assessing performance.

SALES AND PROFIT	2019 \$M	2018 \$M	CHANGE ON PCP \$M	CHANGE ON PCP %
Reported Revenue	525.2	530.3	(5.1)	(1%)
Reported Gross profit	289.9	256.6	33.3	13%
<i>Reported Gross profit %</i>	<i>55.2%</i>	<i>48.4%</i>		
Adjusted EBITDA	130.9	163.5	(32.6)	(20%)
Adjustments ¹	(19.3)	(46.7)	27.4	59%
Reported EBITDA	111.6	116.8	(5.2)	(4%)
Impairments	(351.7)	(184.4)	(167.3)	(91%)
Depreciation / Amortisation	(94.1)	(79.5)	(14.6)	(18%)
Reported PBIT	(334.2)	(147.1)	(187.1)	(127%)
Net Interest	(16.5)	(17.2)	0.8	5%
Reported PBT	(350.7)	(164.3)	(186.3)	(113%)
Income tax expense	69.9	30.3	39.6	131%
Reported NPAT attributable to Mayne Pharma shareholders	(280.8)	(133.9)	(146.8)	(110%)

1. Current year adjustments are included in the table below. Prior period adjustments to Reported EBITDA include \$13.3m for DORYX® returns; abnormal GPD inventory obsolescence and write-downs of \$17.3m; restructuring expenses include employee share cancellation \$16.3m; \$1.6m credit for the revaluation of HPPI warrants; \$1.8m credit for earn-out reassessments, \$0.7m of legal costs associated with the cost of drug pricing investigations and related litigation and \$2.5m to remove the HedgePath Pharmaceuticals Inc. (HPPI) losses attributable to members of the Company.

The reconciliation of reported results and adjusted results for the current year is as follows:

SALES AND PROFIT	REPORTED ATTRIBUTABLE TO MEMBERS JUNE 2019 ¹ \$M	EARN-OUT REASSESSMENTS ² \$M	ASSET IMPAIRMENTS ³ \$M	HPPI – MAYNE PHARMA'S SHARE ⁴ \$M	HPPI WARRANTS ⁵ \$M	DRUG PRICING LITIGATION ⁶ \$M	US RESTATEMENT RE DTA STATE TAXES ⁷	ADJUSTED JUNE 2019 \$M
Revenue	525.2							525.2
Gross profit	289.9							289.9
<i>Gross profit %</i>	<i>55.3%</i>							<i>55.3%</i>
EBITDA	111.6	5.5	-	3.0	8.2	2.7	-	130.9
Depreciation / Amortisation	(94.1)	-	-	0.4		-	-	(93.7)
Asset impairments	(351.7)	-	351.7	-		-	-	-
PBIT	(334.2)	5.5	351.7	3.4	8.2	2.7	-	37.2
Net Interest	(16.5)	-	-	-	-	-	-	(16.5)
PBT	(350.7)	5.5	351.7	3.4	8.2	2.7	-	20.7
Income tax	69.9	-	(79.0)	(0.1)	-	(0.5)	3.2	(6.6)
PAT	(280.8)	5.5	272.7	3.3	8.2	2.2	3.2	14.1

- The values in the above table are values attributable to members of Mayne Pharma and hence include only Mayne Pharma's share of HPPI. The Consolidated Statement of Profit or Loss and Other Comprehensive Income and supporting notes, such as Note 7 for income tax, include 100% of HPPI and hence differ from the above values.
- Earn-out and deferred consideration liabilities re-assessments.
- Asset impairments – intangible asset impairments relating to the change in the current and projected market dynamics for generic products, occurring in 2H19.
- HPPI – Mayne Pharma's share of HPPI's EBITDA loss (\$3.0m).
- Fair value loss (\$8.2m) on restatement of the value of Mayne Pharma's HPPI warrants, after fair value increases in the warrants of \$5.3m in FY17 and \$1.6m in FY18.
- Drug pricing investigations and related litigation costs.
- The Group's effective blended US state tax rate has reduced causing a reduction of the DTA.

The non IFRS financial information is unaudited.

Review of operations

In contrast to the above tables which are based on financial performance attributable to Mayne Pharma shareholders, the following information is provided on a total group basis and hence includes 100% of the revenues and expenses incurred by HPPI where applicable.

Mayne Pharma controls 53.5% of HPPI and has consolidated 100% of HPPI, in accordance with accounting standards, into the financial statements following this Directors' Report.

The Group recorded revenue of \$525.2m, down 1% on pcp and gross profit was \$289.9m up 13% on pcp.

Gross profit margin as a percentage of revenue was 55.2% (2018: 48.4%) which reflects the greater contribution from Specialty Brands which has a higher margin profile, favourable product sales mix in generics and normalised levels of stock obsolescence and DORYX returns.

The reported loss before tax was \$353.7m and the net loss after tax was \$283.8m reflecting \$351.7m (\$272.7m after tax) of asset impairments.

As most of the Company's operations are US based, the weakening AUD compared to the prior year had a favourable P&L translation impact on revenue, gross profit and adjusted EBITDA compared to the pcp. The estimated impact on the current year result, determined by translating the US operations current year performance using the prior year average rate of 0.7753 instead of the current year rate of 0.7153, would have resulted in a decrease to adjusted EBITDA of approximately \$10m. This value excludes foreign currency gains and losses recorded by the Australian operations which largely relate to inventory and financing transactions between the Australian and US operations.

The Company recorded a foreign exchange gain on the net revaluation of the balance sheet (after relevant amounts are taken to the Foreign Currency Translation Reserve ('FCTR')) of \$0.7m in the current year compared to a foreign exchange loss of \$0.2m in the prior period.

The major impact of exchange rates on the Company's balance sheet is recognised in the FCTR which increased by \$52.7m during the year.

Expenses

Net research and development expense after qualifying capitalisation was \$28.5m, an increase in the expense of \$13.0m (84%) on the pcp. Additional R&D spend in Specialty Brands (R&D in this area is generally not capitalised) this period has resulted in the level of R&D capitalisation declining from 68% in the pcp to 43% this year. The increased focus of R&D in the Specialty Brands area is expected to continue with key projects being SUBA®-

itraconazole in Basal Cell Carcinoma Nevus Syndrome ('BCCNS') and Trifarotene for congenital ichthyosis.

	JUNE 2019 \$M	JUNE 2018 \$M
Total R&D costs incurred	50.3	48.5
Development costs capitalised	21.8	33.0
R&D expensed	28.5	15.5

Marketing and distribution expenses increased by \$13.9m to \$76.7m due to the expansion of the dermatology sales team in January 2018 which doubled from 60 to 115 sales representatives as well as the investment in a new specialised field team to market TOLSURA® (SUBA-itraconazole).

Finance costs of \$17.5m (2018: \$17.3m) include interest and line fees on the loan facilities, plus the amortisation of related borrowing costs and the unwinding of discounts associated with earn-out liabilities and deferred liabilities. Borrowing costs are impacted by currency (significant interest expenses are denoted in USD) and the increase in the US Libor rate. This was offset by the cancellation of several interest rate swap contracts which realised a gain of \$1.8m and a gain on the modification of the syndicated loan facility of \$0.5m. The Company renewed its financing facilities during December achieving a lower margin.

Impairments of \$351.7m (2018: \$184.4m) were recognised following a detailed review of the Company's intangible assets as at 30 June 2019. The review considered the current and projected US market dynamics for the portfolio and the industry.

The impairments included the following:

- Specific pipeline products (development expenditure) - \$37.8m
- Specific Canadian asset - \$1.5m
- GPD – Other Cash Generating Unit (CGU) intangible assets - \$312.4m.

Administration and other expenses increased by \$24.7m to \$171.9m. This category includes non-cash and other non-operating items such as:

- amortisation of intangible assets which was \$78.9m (2018: \$70.2m),
- the fair value restatement of HPPI warrants \$8.2m,
- the restatement of earn-out liabilities \$5.5m (2018: \$1.8m credit),
- share based payments expense \$9.0m (2018: \$14.5m),
- drug pricing investigations and related litigation costs \$2.7m (2018: \$0.7m),
- restructuring expenses were nil (2018: \$5.8m) and FX losses were nil (2018: \$0.2m).

Excluding these items, administration and other expenses increased \$11.2m to \$67.7m and reflects \$2.0m of additional legal costs primarily for patent litigation and a one-off settlement charge, unabsorbed building costs for the new Greenville facility of \$3.5m and unfavourable FX movements of \$3.5m.

Tax

The tax benefit of \$70.0m comprised:

- Current period income tax expense for the year to 30 June 2019 of \$1.0m;
- An increase in current year tax benefit in respect of prior years of \$0.1m; and
- An increase in income tax benefit of \$70.9m relating to the movement in deferred tax assets and liabilities, principally from the impairment expense.

Financial position

Set out below is a summary of the financial position as at 30 June 2019 compared to the position as at 30 June 2018.

BALANCE SHEET EXTRACT	NOTES	2019 \$M	2018 \$M	CHANGE ON PCP \$M	CHANGE ON PCP %
Cash		89.0	87.3	1.7	2%
Receivables		256.6	252.7	3.9	2%
Inventory		100.3	82.2	18.1	22%
PP&E		236.0	230.1	5.9	3%
Intangible assets and goodwill		797.6	1,054.5	(256.9)	(24%)
Other assets		156.8	123.7	33.1	27%
Total assets		1,636.3	1,830.5	(193.9)	(11%)
Interest-bearing debt		369.4	374.2	(4.8)	(1%)
Trade and other payables		130.0	152.6	(22.6)	(15%)
Other financial liabilities		73.9	17.8	56.1	315%
Other liabilities		49.0	50.7	(1.7)	(3%)
Total liabilities		622.3	595.3	27.0	5%
Equity		1,014.0	1,235.2	(221.2)	(18%)

The material changes to the operating assets and liabilities of the business were as follows:

Cash

Cash increased by \$1.7m compared to 30 June 2018. Refer below for further commentary. Net operating cashflow was an inflow of \$106.6m (2018: \$121.5m), with investing cashflow \$91.7m, leaving free cashflow of \$14.9m. Cash was utilised to reduce borrowings.

Inventory, receivables and trade payables

Inventory increased by \$18.1m (of which \$4.2m was due to change in USD exchange rate) and receivables increased by \$3.9m. Trade and other payables decreased by \$22.6m compared to the prior period.

Intangible assets and goodwill

Intangible assets decreased by \$256.9m compared to the balance at 30 June 2018. The movement comprised of:

- An increase of \$21.4m for capitalised development costs;
- An increase of \$104.5m for additions being mainly LEXETTE™ and generic EFUDEX®;
- A decrease of \$78.9m for amortisation;
- A decrease of \$351.7m for impairments; and
- An increase of \$47.8m due to foreign currency translation as the AUD / USD exchange rate decreased from 0.7407 at 30 June 2018 to 0.7022 at 30 June 2019.

Property, plant & equipment

Property, plant and equipment increased by \$6.0m compared to the balance at 30 June 2018. The movement comprised of:

- An (net) increase of \$11.9m for additions;
- A decrease of \$15.6m for depreciation; and
- An increase of \$9.7m due to foreign currency translation.

The strategic investments at Salisbury, South Australia and Greenville, North Carolina were completed in FY18 to support the pipeline of products under development, the transfer in-house of products manufactured by third parties and commercial contract manufacturing.

Interest bearing liabilities

Interest bearing liabilities decreased to \$369.4m from \$374.2m at 30 June 2018. USD denoted Interest-bearing liabilities decreased by US\$94m while AUD borrowings increased by \$110m resulting in net repayments of \$22.6m. The net repayments were largely offset by the AUD/USD exchange rate movement.

Other financial liabilities

Other financial liabilities as at 30 June 2019 include the earn-out liabilities and deferred consideration for the generic NUVARING® distribution rights, LEXETTE distribution rights, generic EFUDEX distribution rights and various other product acquisitions and distribution rights.

Other financial liabilities increased by \$56.1m from 30 June 2018 due to:

- An increase of \$1.8m due to the non-cash unwinding of the discount for the various earn-out liabilities;
- An increase of \$55.9m due to asset acquisitions (mainly in relation to LEXETTE and generic EFUDEX);
- An increase of \$5.5m due to re-assessments of various earn-out liabilities;
- A decrease of \$9.3m due to payments made;
- An increase for mark to market valuation of interest rate swaps of \$0.4m; and
- An increase relating to foreign currency translation of \$1.8m.

Equity

Equity movements include the current year loss of (\$279.9m) and other comprehensive income of \$45.5m for a net movement of (\$234.4m).

Cash flow

A summary of the net operating cash flows is as follows:

	2019 \$M	2018 \$M
Operating cash flow before working capital movements	135.7	116.7
Working capital (investment) / release	(29.1)	4.8
Net Operating cash flows	106.6	121.5

Net operating cash for FY19 was an inflow of \$106.6m after including \$21.0m of net tax refunds, \$13.5m of net interest payments and \$29.1m net working capital investment due to an increase in payment terms to a key wholesaler.

Other notable cash flows during the period included:

- \$47.6m in payments for research and development (includes expensed and capitalised);
- Earn-out and deferred settlement payments totalling \$9.3m;
- Payments for intangibles of \$48.7m; and
- \$11.9m in capital expenditure across the Group.

Cash on hand at 30 June 2019 was \$89.0m representing an increase of \$1.7m from 30 June 2018.

The Company had bank debt of \$369.4m at 30 June 2019.

Pipeline

The Company continues to commit substantial resources in terms of people, and research and development spend to develop and advance its pipeline globally. In FY19, the Company incurred, in total cost terms, \$50.3m in research and development of which 43% (2018: 68%) was capitalised over the period to be amortised in the future in accordance with Australian Accounting Standards.

During the period, the Company received FDA approval for TOLSURA (SUBA-itraconazole) anti-fungal capsule which launched in the US in January 2019 through a new hospital-based field team calling on infectious disease and other healthcare professionals. In addition, the Company launched LEXETTE (halobetasol) foam used to treat psoriasis and five generic products in the US including generic EFUDEX cream, generic FENTORA® tablet, generic KAPVAY® tablet, generic BROMFED® DM syrup and generic butalbital/APAP capsule.

Mayne Pharma's generic pipeline includes more than a dozen products pending approval at the FDA including a generic NUVARING, which is the largest contraceptive sold in the US contraceptive market with no generic equivalents today.

In terms of the brand programs, the Company continues to progress the commercialisation of its patented formulation of itraconazole for the treatment of certain fungal conditions and as a potential treatment for certain cancers. SUBA-itraconazole is a proprietary, patented formulation that enhances the solubility and absorption of conventional itraconazole formulations. SUBA-itraconazole was launched in the US, Argentina, Mexico and Italy during the year to treat fungal infections and is now sold in seven countries. The Company also assumed control of the SUBA-itraconazole BCCNS program from HPPI. Mayne Pharma now controls all development and commercial aspects of this program and plans to commence a phase III pivotal clinical trial in FY20. The increased focus of R&D in the Specialty Brands area is expected to continue with key projects being SUBA-itraconazole in BCCNS and Trifarotene in congenital ichthyosis.

Reporting Segments

The Consolidated Entity operates in four reporting segments, being Generic Products ('GPD'), Specialty Brands ('SBD'), Metrics Contract Services ('MCS'), and Mayne Pharma International ('MPI').

Refer to Note 2 for further information about the reporting segments.

GPD

\$MILLION	2019 \$M	2018 \$M	CHANGE %
Revenue	320.8	385.7	(17%)
Gross profit	164.5	177.4	(7%)
Gross profit %	51%	46%	

Nature of operations

GPD's revenues and gross profit are derived principally from the manufacture and distribution of generic pharmaceutical products in the US.

FY19 performance

The GPD reporting segment's sales were \$320.8m, down 17% on FY18 and gross profit was \$164.5m down 7% on FY18 impacted largely by competitive pressure on key products.

In US dollar terms, sales were US\$229.5m, down 23% on pcp with dofetilide sales being the major contributor declining US\$54m to US\$13m in FY19. Dofetilide sales were impacted by pricing pressure, market share loss and one-off shelf stock adjustments. Liothyronine sales whilst up 86% on pcp to US\$43m, were also impacted in the 2HFY19 by new competition with sales declining 42% on the 1HFY19 in US dollar terms.

SBD

\$MILLION	2019 \$M	2018 \$M	CHANGE %
Revenue	91.6	44.7	105%
Gross profit	79.8	37.5	113%
Gross profit %	87%	84%	

Nature of operations

SBD's revenues and gross profit are derived principally from the marketing and distribution of specialty branded pharmaceutical products in the US.

FY19 performance

The SBD reporting segment's sales were \$91.6m, up 105% on FY18 and gross profit was \$79.8m up 113% on FY18.

In US dollar terms, SBD's sales were US\$65.5m, up 89% on pcp. All products contributed to the growth benefiting from the sales team expansion in 2018 with FABIOR® up 54%, SORILUX® up 26% and the DORYX family up 153% versus pcp. The strong growth in DORYX reflects elimination of the abnormal one-off DORYX returns which impacted the prior period and favourable product sales mix. The launch of LEXETTE in February 2019 also contributed to the growth with total weekly prescriptions averaging 680 across the June quarter.

MCS

\$MILLION	2019 \$M	2018 \$M	CHANGE %
Revenue	72.2	63.1	14%
Gross profit	35.5	33.7	6%
Gross profit %	49%	53%	

Nature of operations

MCS' revenue and gross profit are derived from the provision of contract pharmaceutical development, manufacturing and analytical services to third-party customers principally in the US.

FY19 performance

The MCS reporting segment's revenues were \$72.2m up 14% on FY18 and gross profit was \$35.5m up 6% on FY18.

In US dollar terms, sales were up 6% on pcp to US\$51.6m. MCS is benefiting from the investments made in Greenville over the last three years to transform manufacturing capacity and capability. During FY19, MCS added three further commercial manufacturing clients up from one in the prior period with manufacturing revenues representing 5% of the segment sales.

MPI

\$MILLION	2019 \$M	2018 \$M	CHANGE %
Revenue	40.7	36.8	11%
Gross profit	10.0	8.0	25%
Gross profit %	25%	22%	

Nature of operations

MPI's revenues and gross profit are derived principally from the Australian manufacture and sale of specialty branded and generic pharmaceutical products globally (ex-US) and provision of contract development and manufacturing services to third party customers within Australia.

FY19 performance

The MPI reporting segment's revenues were \$40.7m up 11% and gross profit was \$10.0m, up 25% on FY18.

MPI benefited from growing sales of itraconazole and morphine globally, new third-party contract development revenues and milestone payments from the out-licensing of key specialty branded products globally.

Strategy

Mayne Pharma is using its world-class oral drug delivery expertise and US commercial infrastructure to build a global speciality pharmaceutical company. The Company is focused on increasing the breadth of its product portfolio, technologies and market access to deliver unmatched patient service and service delivery levels to our key partners.

The Company's core strategic priorities include the following:

KEY STRATEGIC PRIORITIES	ACTIVITIES
<ul style="list-style-type: none">Therapeutically focused expansion of product portfolio	<ul style="list-style-type: none">Best-in-class product selection and sourcing to improve patient reach and impact in each core therapeutic areas focusing on:<ul style="list-style-type: none">Products aligned with core therapeutic areas (eg. dermatology, women's health, infectious disease)Broadening medical benefits through label extensionsTargeting indications with high unmet needLeveraging hybrid product model to maximise diversified distribution platform
<ul style="list-style-type: none">High quality development supported by reliable supply	<ul style="list-style-type: none">Concept-to-commercialisation MCS client offeringEmphasis on cost efficiency and flexibilitySourcing and supply chain aligned to key product marketsUninterrupted product supply to patients and clientsStrong external network of technical partners
<ul style="list-style-type: none">Multi-channel, agile commercial approach	<ul style="list-style-type: none">Maximise value of on market productsDevelop infrastructure and commercial activities to move closer to the patientAlternative business & distribution modelsUtilise commercial engine to drive new product selectionGlobalise key strategic franchises (eg. SUBA, Dermatology)

Material business risks

The Board accepts that taking and managing risk is central to building shareholder value and that the Board is responsible for the Group's risk management strategy. Management is responsible for implementing the Board's strategy and for developing a control infrastructure designed to identify and mitigate risks across operations.

The Company has implemented a Risk Management Policy that includes a risk framework with a detailed, structured approach to systematically identify, rank, mitigate, and monitor risks. This effort, led by the Governance, Risk & Control (GRC) function, is additive to ongoing risk management responsibilities that all employees engage in as they accomplish their daily tasks according to Company requirements. The Company maintains a risk register and material risks are regularly reported on and discussed with management, the Audit & Risk Committee and the Board. Further details of the Company's approach to risk identification and management are outlined in its Corporate Governance Statement.

The following details some of the material risks that could affect Mayne Pharma’s business and operations but are not the only risks Mayne Pharma faces. Other risks besides those detailed below could adversely affect Mayne Pharma’s business and operations.

RISK	NATURE OF THE RISK	ACTIONS / PLANS TO MITIGATE
In-market pricing and competitive intensity	<ul style="list-style-type: none"> Competitive dynamics for a product become unfavourable Sales of our products may be adversely impacted by continuing consolidation of the customer base New competitors enter a market or competitors increase market share Inability to obtain or delays in obtaining satisfactory pricing and reimbursement from government bodies, national health authorities and other third parties 	<ul style="list-style-type: none"> Recruitment of experienced sales and marketing personnel Disciplined and risk balanced product selection process Strong systems and processes to monitor and manage the performance of each product and customer relationship Diversify channels to market
Regulatory compliance	<ul style="list-style-type: none"> Loss of regulatory compliance certification for production facilities Violation of healthcare compliance requirements Violation of antibribery or antitrust requirements 	<ul style="list-style-type: none"> Recruitment of experienced personnel in Quality, Production and Compliance Establish a robust control environment with relevant policies and procedures Strong systems and processes to manage and monitor compliance
Product cost inflation	<ul style="list-style-type: none"> Increasing cost of active pharmaceutical ingredients and other components Interruptions to supply of raw materials and drug product 	<ul style="list-style-type: none"> Exclusive supply arrangements, where appropriate Distribution arrangements with partners allow for rising input costs to be passed through to customers Back-up supply of key raw materials
Foreign exchange movements	<ul style="list-style-type: none"> Adverse movements in exchange rates 	<ul style="list-style-type: none"> Hedging of balance sheet and net receipts in accordance with Company policy
Product liability	<ul style="list-style-type: none"> Serious adverse event with consumers and potential product liability risks in marketing and use of products Serious adverse events with participants in clinical trials 	<ul style="list-style-type: none"> Establishment and maintenance of systems to track medical information, pharmacovigilance (ie. monitoring the effects of medical drugs, in particular to identify and evaluate previously unreported adverse events), quality and (where appropriate) usage (eg. to identify potential abuse) Allocate or share risk with distribution partners where appropriate Appropriate insurance coverage
Intellectual property	<ul style="list-style-type: none"> Infringement of third-party intellectual property rights Loss or infringement of owned intellectual property 	<ul style="list-style-type: none"> Disciplined product selection process taking into account possible intellectual property infringement Implementation of a robust intellectual property strategy Allocate or share risks with manufacturing partners where appropriate
Asset impairments	<ul style="list-style-type: none"> The recoverable amount of non-current assets, including brands and goodwill may be assessed to be less than the carrying value and an impairment charge may be recognised 	<ul style="list-style-type: none"> Assets are tested regularly for impairment Capitalisation policies and useful lives of assets are reviewed by external auditors
Acquisition risk	<ul style="list-style-type: none"> Integration of acquisitions can take longer than expected, divert management attention and not deliver the expected benefits 	<ul style="list-style-type: none"> Conduct detailed due diligence of acquisitions and engage third parties where relevant for expert advice Preparation of detailed operational/integration plans and ongoing monitoring of acquisitions following completion
Environmental, health and safety	<ul style="list-style-type: none"> Failure to comply with environmental health and safety regulations, laws and industry standards Injury to employees or contractors Failure to safely and appropriately handle hazardous and toxic materials 	<ul style="list-style-type: none"> Regional Environmental, Health and Safety ('EHS') Management Systems have defined policies, procedures and work practices for the elimination or mitigation of EHS hazards and risks
Information technology	<ul style="list-style-type: none"> Cyber threats and data security Disruptions or failures in our information technology systems and network infrastructure 	<ul style="list-style-type: none"> Recruitment of experienced IT personnel Implementation of protective measures such as firewalls, antivirus, data encryption, routine back-ups, system audits, disaster recovery procedures
Financial fraud	<ul style="list-style-type: none"> Purposely publishing inaccurate financial data at the half year or at the end of the fiscal year Falling prey to an internal scheme that has a material financial impact on the Company 	<ul style="list-style-type: none"> Hiring and cooperating with a reputable external accounting firm tasked with auditing our financial statements and evaluating our control environment Recruitment of experienced financial controls personnel Implementation and enforcement of policies and procedures that foster a robust control environment
Catastrophic facility / equipment failure	<ul style="list-style-type: none"> Loss of buildings and/or key equipment Exposure to “failure to supply” penalties 	<ul style="list-style-type: none"> Development of contingency plans to move production across our multiple facilities and among our CMO partners if facilities or equipment become unavailable Purchase of insurance coverage to minimise the Company’s exposure to penalties

The above list does not represent an exhaustive list and it may be subject to change based on underlying market events and developments in the Company’s operations.

Outlook

In FY20, the Company expects stronger results driven by the recent specialty brand launches of TOLSURA and LEXETTE, growth of the generic and proprietary dermatology and women's health portfolios and accelerated growth of Metrics Contract Services driven by additional headcount, the expanded manufacturing and testing footprint in Greenville and delivery of the pipeline of committed business.

The Company is targeting eight new product launches by the end of CY20 of which two are already approved and three have no generic equivalents today.

In addition, various initiatives at the Company's manufacturing sites in Greenville and Salisbury are expected to drive greater operational efficiencies and improved financial performance across FY20 and beyond. The Company also expects to further optimise its cost base through reducing operating expenses via more controlled spending and realising significant cost savings from product transfers in house or to new contract manufacturers.

DIVIDENDS

The Directors have not declared an interim or final dividend for the 2019 financial year.

EVENTS SUBSEQUENT TO THE REPORTING PERIOD

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 Group.

DIRECTORS' EXPERIENCE AND SPECIAL RESPONSIBILITIES

MR ROGER CORBETT AO, BCom, FAIM

Independent Chairman
Age 76
Appointed 17 November 2010

Mr Corbett joined the Board of Mayne Pharma Group Limited in November 2010 and was appointed Chairman in January 2011. Mr Corbett has been involved in the retail industry for over 50 years. He started unloading trucks at the Grace Bros Chatswood store in the early 60s and rose through the ranks to hold the positions of Merchandise Director and Stores Director of Grace Bros and subsequently Operations Director of David Jones. In 1990 Mr Corbett was appointed to the board of Woolworths Limited and to the position of Managing Director of BigW, later becoming Chief Operating Officer and then CEO of Woolworths Limited. Mr Corbett served on the board of Woolworths from 1990 until his retirement in 2006.

Mr Corbett has previously held the following positions: CEO of Woolworths Limited, Chairman of Fairfax Media Limited, Chairman of PrimeAg Australia Limited, member of the Board of the Reserve Bank of Australia, member of the Board of Wal-Mart Stores, Inc., Chairman of Australian Leisure and Hospitality Group Pty Limited (ALH Group), Chairman of the World Food Forum (CIES), Paris, Chairman of the Children's Hospitals of Westmead and Randwick and Chairman of Salvation Army Advisory Board - Australian Eastern Territory.

Mr Corbett's current Executive and Board responsibilities are Chairman of Molopo Energy Limited and Chairman of Beovista Pty Ltd.

In addition to being Chairman of the Mayne Pharma Board, Mr Corbett is Chair of the Remuneration and People Committee and is a member of the Nomination Committee.

MR SCOTT RICHARDS

Executive Director and Chief Executive Officer
Age 56
Appointed 13 February 2012

Mr Richards has more than 28 years' international experience in the pharmaceutical industry and has worked in Europe, the US and Asia. Prior to joining Mayne Pharma, Mr Richards spent 10 years in Europe in a variety of leadership roles including President, Europe Middle East and Africa and President, Global Commercial Operations for Mayne Pharma Limited (acquired by Hospira in 2007). He also served on the Group Management Board of Actavis for 4 years where he was responsible for the firm's global injectable/hospital business operations. Prior to working in Europe, Mr Richards spent 14 years with FH Faulding and Co (acquired by Mayne Nickless in 2001) in a variety of roles including leading Faulding Pharmaceuticals Asia Pacific operations together with spending 5 years with Faulding in the US leading business development and portfolio management operations. Mr Richards' experience spans sales and marketing, regulatory/medical affairs, supply chain, business development, mergers and acquisitions, finance, intellectual property and manufacturing.

HON RON BEST

Independent Non-Executive Director
Age 70
Appointed 26 July 2006

The Hon Ron Best is a highly respected former member of the Victorian Parliament (1988 to 2002), having held senior positions in the National Party of Australia (Victoria) including Parliamentary Secretary, Shadow Minister for Housing and Spokesman for Health, Housing, Racing, Sport and Recreation. Mr Best has also been a member of various Parliamentary Committees including the Public Accounts and Estimates Committee, the Environmental and Natural Resources Committee and a Board Member of the Victorian Health Promotion Foundation. Prior to his political career, Mr Best was the owner of a successful food distribution business and General Manager of the Glacier Food Group. Since retiring from politics in 2002 Mr Best has consulted for privately-owned companies in the food services industry.

Mr Best is Chairman of the Nomination Committee and a member of the Audit & Risk Committee and the Remuneration and People Committee.

MR PATRICK BLAKE

Independent Non-Executive Director
Age 56
Appointed 28 June 2018

Mr Blake, a US resident, has over 30 years of global healthcare industry experience including more than 20 years at McKesson Corporation, one of the largest healthcare services and information technology companies globally, and more than 10 years at Baxter Healthcare Corporation. Most recently, he was Executive Vice President of McKesson Corporation and Group President of McKesson Technology Solutions which services the health IT needs of hospitals and health systems, payers, physicians, homecare agencies, retail pharmacies and manufacturers, a position he held from 2009 until 2017. Previously, he was President of McKesson Specialty Health, a business focussed on the US specialty/biotech sector which was McKesson's fastest growing business for three years during his leadership. He was also President of Customer Operations for McKesson Pharmaceutical (US) from 2000 to 2006, leading commercial sales and operations for the wholesale distribution of branded, specialty and generic pharmaceuticals and other related products.

MR FRANK CONDELLA

Independent Non-Executive Director
Age 65
Appointed 30 May 2018

Mr Condella, a US resident, has over 30 years of experience in senior executive roles in the global pharmaceutical industry. His operating experience includes Chief Executive Officer of Juniper Pharmaceuticals, a US publicly-listed CDMO and specialty pharmaceutical company, which was subsequently sold to Catalent. Previously he served as Chief Executive Officer of Skyepharma Plc, President of European operations at IVAX (Teva), Chief Executive Officer of Faulding Pharmaceuticals, Vice President of Specialty Care Products at Roche and Vice President and General Manager of the Lederle Standard Products (Pfizer). Mr Condella's previous board experience includes Chairman of Skyepharma Plc until it merged with Vectura ,

Vice Chairman of Vectura Plc, Independent Director of Prosonix Ltd, Independent Director of Fulcrum Pharma plc, and Chairman of the PKD Foundation. He currently also serves as an Independent Director for Fertin Pharma A/S (Denmark) and Palladio Biosciences Inc (US). Mr Condella is a member of the Science, Technology and Medical Committee.

MS NANCY DOLAN, BA, LLB

Independent Non-Executive Director

Age 68

Appointed 21 September 2016

Ms Dolan has over 30 years' experience in the legal and commercial services sector. Ms Dolan is currently Chair of the Professional Conduct Oversight Committee at Chartered Accountants Australia and New Zealand. Ms Dolan has an honours degree in law from Victoria University of Wellington and an arts degree from the University of Canterbury in New Zealand. She was previously General Counsel and a Principal Officer at the University of Sydney, a Partner at PricewaterhouseCoopers responsible for legal affairs in the Asia Pacific region and a Partner at Mallesons Stephen Jacques (now King & Wood Mallesons). Ms Dolan was previously on the Advisory Board of the Sydney Medical School, on the Professional Standards Council for the Salvation Army, a member of the Advisory Committee for Salvos Legal and on the Salvation Army Advisory Board (Eastern Territory).

Ms Dolan is a member of the Audit & Risk Committee and the Nomination Committee.

MR BRUCE MATHIESON

Independent Non-Executive Director

Age 76

Appointed 16 February 2007

Mr Mathieson is currently a Director and was the former Chief Executive Officer of ALH Group, a joint venture between Woolworths Limited and the Mathieson Family. The ALH Group owns approximately 325 hotels and 520 retail outlets across Australia and employs more than 16,000 staff. Mr Mathieson has operated in the hotel, leisure and hospitality industry since 1974 and is a well-respected member of the Australian business community. He has previously served as a Director of the Carlton Football Club. He is trained as an engineer and brings management and transactional experience from a number of industries to the Board.

PROF BRUCE ROBINSON, AM, MD, MSC, FRACP, FAAHMS, FAICD

Independent Non-Executive Director

Age 63

Appointed 26 August 2014

Professor Robinson, a practising Endocrinologist at Sydney's Royal North Shore Hospital, is Former Dean of University of Sydney's Sydney Medical School. Professor Robinson has been the head of the Cancer Genetics Unit at the Kolling Institute of Medical Research, Royal North Shore Hospital since 1989. Since 2001, Professor Robinson has been Chairman of Hoc Mai Foundation, a major program in medical and health education and exchange with Vietnam. He is a Non-Executive Director of Cochlear Limited, Lorica and QBiotics Group Limited. He is a Board Member of the Woolcock Institute, is Chair of National Health and Medical Research Council and Chair of the Medical Benefits Review Taskforce.

Prof Robinson is Chairman of the Science, Technology and Medical Committee.

MR IAN SCHOLES BCom, CA

Independent Non-Executive Director

Age 64

Appointed 17 October 2007

Mr Scholes has extensive financial and corporate advisory experience, both in Australia and internationally. Mr Scholes held a number of senior roles within Merrill Lynch Australia, including Managing Director and Vice Chairman of Investment Banking. Previously Mr Scholes held the position of Executive General Manager at National Australia Bank Limited, running the corporate and institutional banking division. Mr Scholes is currently a Partner and Chief Executive Officer of Chord Capital Pty Ltd. Mr Scholes has previously held positions on the Board of St Vincent's Health as Chairman of the St Vincent's Foundation and was a former Director of SDI Limited.

Mr Scholes is Chairman of the Audit & Risk Committee and a member of the Remuneration and People Committee.

COMPANY SECRETARY

Mr Nick Freeman, BCom, CA (Group CFO and Company Secretary) was appointed as the Company Secretary on 24 May 2017. Mr Freeman is a Chartered Accountant with 30 years' experience in the accounting and finance profession. Mr Freeman has extensive experience in the areas of business development, mergers and acquisitions, integration management, tax, financial planning and reporting, risk management, treasury and investor relations.

DIRECTORS' INTERESTS IN SHARE CAPITAL AND OPTIONS

The relevant interest of each Director in the share capital of the Company as at the date of this report is as follows:

	FULLY PAID ORDINARY SHARES	RESTRICTED ORDINARY SHARES ISSUED UNDER LONG TERM INCENTIVE PLAN WITH LIMITED-RECOURSE LOANS
Mr R Corbett	10,440,569	-
Mr S Richards	5,985,369	21,457,254
Mr P Blake	-	-
Hon R Best	1,587,217	-
Mr F Condella	181,835	-
Ms N Dolan	101,772	-
Mr B Mathieson	98,777,583	-
Prof B Robinson	634,895	-
Mr I Scholes	2,158,636	-

UNISSUED SHARES UNDER OPTION

As at the date of this Directors' Report there were 1,820,000 unissued ordinary shares under option (2,020,000 at the reporting date). Details of these options are as follows:

DATE OPTIONS GRANTED	EXPIRY DATE	EXERCISE PRICE	NUMBER UNDER OPTION
1 May 2014	21 October 2019	\$0.5923	120,000
1 May 2014	30 November 2019	\$0.6754	500,000
19 August 2014	2 July 2019	\$0.8109	200,000
19 August 2014	28 August 2019	\$0.7682	600,000
29 January 2015	1 February 2020	\$0.5347	600,000
Total			2,020,000

Option holders do not have any right, by virtue of the option, to participate in any share issue of the Company.

SHARE OPTIONS GRANTED

No share options were granted during the financial year.

Further details of options are contained in Note 26 of the financial statements.

SHARES ISSUED AS A RESULT OF THE EXERCISE OF OPTIONS

During the financial year options have been exercised to acquire a total of 4,604,000 fully paid ordinary shares in Mayne Pharma Group Limited at a weighted average exercise price of \$0.3669 per share.

NON-AUDIT SERVICES

The Company's auditor, EY Australia ('EY'), provided the non-audit services listed below. The Directors are satisfied that the provision of these non-audit services is compatible with the general standard of independence for auditors imposed by the Corporations Act 2001.

The nature and scope of each type of non-audit service provided means that auditor independence was not compromised.

EY received or are due to receive the following amounts for the provision of non-audit services:

	2019 \$	2018 \$
Taxation services	176,000	105,465
Other assurance	223,500	280,029
Total	399,500	385,494

INDEMNIFICATION AND INSURANCE OF OFFICERS AND INDEMNIFICATION OF AUDITORS

The Company's constitution (rule 11.1(a)) requires the Company to indemnify every officer of the Company and its wholly owned subsidiaries against liabilities incurred in their role as officer, only to the extent permitted by the Corporations Act 2001. The indemnity will not apply to liabilities arising out of conduct involving a lack of good faith. The Company has entered into a Deed of Access, Insurance and Indemnity with each of the Directors, KMP, others holding officer positions in the Company or any of its wholly owned subsidiaries and the Company's previous appointee to the HPPI Board. Each Deed of Access, Insurance and Indemnity indemnifies the relevant officer, to the extent permitted by law, against any liability incurred by the relevant officer as an officer of the Company or as an officer of a subsidiary, including legal costs (for an unspecified amount). The Deeds of Access, Insurance and Indemnity also require the Company to (subject to the Corporations Act 2001) use its best efforts to effect and maintain a D&O policy covering the relevant officers during each officer's term of office and for seven years thereafter.

During the financial year, the Company maintained an insurance policy which indemnifies the Directors and officers of the Company and its subsidiaries in respect of any liability incurred in the performance of their duties as Directors or officers of the Company or its subsidiaries, other than for matters involving a wilful breach of duty or a contravention of sections 182 or 183 of the Corporations Act 2001 as permitted by section 199B of the Corporations Act 2001. The Company's insurers have prohibited disclosure of the amount of the premium payable and the level of indemnification under the insurance contract.

To the extent permitted by law and professional regulations, the Company has agreed to indemnify its auditors, EY, as part of the terms of its audit engagement agreement against claims by third parties arising from the audit but excluding any claims which are finally determined to have resulted from EY's negligent, wrongful or wilful acts or omissions. No payment has been made to indemnify EY during or since the financial year. Such an indemnity is permitted under rule 11.1(a) of the Company's constitution.

ENVIRONMENT, HEALTH AND SAFETY (EHS) REGULATION AND PERFORMANCE

The Group's operations are subject to various EHS laws and regulations and, where required, the Group maintains EHS licenses and registrations in compliance with applicable regulatory requirements. The Group has mechanisms in place to monitor for changes to regulatory requirements and ensure ongoing compliance with any new requirements.

The Group has EHS policies and procedures in place designed to ensure compliance with all EHS regulatory requirements and to continuously improve the health and safety of our workplace and environmental sustainability of our operations.

The EHS function continues to refine and improve the Company's standards, processes and performance through the ongoing development and maintenance of an EHS management system focussed on the identification and assessment of EHS hazards and effective management of EHS risks by applying sound risk management principles.

The Group monitors EHS outcomes on a regular basis and provides reports to various internal and external stakeholders including, without limitation, in relation to performance data such as injury rates, waste disposal, waste water and storm discharges and emissions. The operating sites in Salisbury and Greenville are subject to periodic or random inspections by EHS regulators; several inspections occurred during the year by the relevant authorities.

The Directors are not aware of any material breaches of EHS regulations by the Group.

ROUNDING

Amounts in this report and in the financial report have been rounded off in accordance with ASIC Legislative Instrument 2016/191 issued by the Australian Securities and Investments Commission, to the nearest thousand dollars or, in certain cases, to the nearest dollar.

AUDITOR'S INDEPENDENCE DECLARATION

The Auditor's Independence Declaration has been received from EY and is included on page 23 of this report.

Letter from Chairman of Remuneration and People Committee

Dear Shareholder,

On behalf of the Board of Directors, we are pleased to present Mayne Pharma's Remuneration Report for the financial year ended 30 June 2019.

It has been a challenging year for Mayne Pharma driven by competitive pressures in the US generic market. In response to these market dynamics Mayne Pharma has undertaken a number of actions in FY19 to better align its generic business with market realities and refocus the business in sustainable and growing categories and channels. These changes position the business well for the future and ultimately aim to reduce earnings volatility and maximise returns for shareholders.

Your Board is committed to an executive remuneration framework that is focused on aligning shareholder and management interest by adopting a remuneration policy with a significant weighting to at-risk and long-term incentives (LTI). Executive pay design comprises market competitive fixed annual remuneration (FAR) combined with the opportunity to build wealth together with shareholders through the LTI.

As a result, Mayne Pharma has removed short-term incentives (STI) for senior executives and a stronger proportion of total remuneration is in the form of LTI with performance hurdles aligned to shareholder interests.

We believe an equity-based LTI is important to ensure close alignment with shareholders and motivates executives to focus on corporate strategies that will deliver long-term growth of shareholder value. The LTI is in the form of a share loan scheme (effectively operates like a 5-year option) and executives will only receive a benefit from the LTI program if the share price increases, with loan shares progressively vesting at continuously increasing performance hurdles.

The challenges faced by Mayne Pharma over the last few years are reflected in the financial results of the company and ultimately in the remuneration outcomes for senior executives. Since the introduction of the Executive Share Loan Scheme (ESLS) in FY15, which superseded the option scheme as the new LTI, less than 7% of loan shares have vested and only 84,999 loan shares have been exercised. The total cash benefit realised to all employees from the share loan scheme for the period FY15 to FY19 has been \$80,749.

Based on the 51c share price at 30 June 2019, no employee options or loan shares were in the money and could be exercised, which demonstrates the strong alignment of this program with our shareholders.

While 102m loan shares and 1.8m options remain outstanding, representing theoretical dilution of 6.6% at balance date, the actual dilution to shareholders is 0%.

Your Board and management team have significant ownership in Mayne Pharma and are highly motivated to turn around performance and generate shareholder value. Minimum shareholding guidelines are required for all Key Management Personnel (KMP) with Non-Executive Directors expected to accumulate one times base fee within 3 years of appointment, the CEO is expected to accumulate one and half times base salary and other executive KMP are expected to accumulate between 70% to 110% of their base salary.

Key changes in the FY19 remuneration report

- Mr Phil Hodges retired from the Board of Directors following the 2018 Annual General Meeting on 29 November 2018.
- Mr Brant Schofield was appointed to the role of Executive Vice President Specialty Brands on 8 October 2018.
- There was a significant reduction in loan shares issued to management (10.1m in FY19 versus 73.6m in FY18) to reflect the change in timing of share awards to align with the half year and full year results announcement. The loan shares issued in FY19 relate largely to the CEO's annual award, which was approved at the 2018 AGM.
- The CEO's annual ESLS participation was increased to 200% (previously 150%) following a review of CEO remuneration of Australian and US comparators by KMPG-3dc.
- US Non-Executive Director fees were adjusted on 1 January 2019 to US\$131,400 (being the equivalent of Australian Non-Executive Director fees in A\$ but expressed in US\$) to compensate for exchange rate movements and more closely align with US market rates, following a comparator review of NED fees.

We have also worked to streamline and improve our report this year and hope you find it relevant and useful in understanding our remuneration policies and practices.

There have been no changes to remuneration policy this year. Your Board is currently reviewing Mayne Pharma's remuneration framework taking into consideration shareholder and stakeholder feedback including the structure of the LTI plan. Recognising the challenges our business has faced this year, your Board has decided there will be no increase in KMP salaries in FY20.

We hope you find this report better explains our remuneration structure and welcome any feedback you may care to provide.

Yours sincerely



Roger Corbett, AO
Mayne Pharma Chairman

REMUNERATION REPORT (AUDITED)

This report outlines the specific remuneration arrangements in place for the KMP and the broader remuneration policies and philosophy adopted by the Board. KMP are those persons in the Group having authority and responsibility for planning, directing and controlling the major activities of the Company and the Group, directly or indirectly, including any Director (whether executive or otherwise) of the Company.

There were no significant changes to remuneration policies during the year.

There was however a significant reduction in loan shares issued to management (10.1m in FY19 versus 73.6m in FY18) to reflect the change in timing of the share awards to align with the half year and full year results announcement. The loan shares issued in FY19 relate largely to the CEO's annual award which was approved at the 2018 AGM and a new starter.

This Report forms part of the Directors' Report and has been audited in accordance with section 300A of the Corporations Act 2001.

1. KEY MANAGEMENT PERSONNEL DETAILS

The table below outlines the KMP of the Group during the current financial period. Unless otherwise indicated, the individuals were KMP for the entire financial year and up until the date of this report.

Non-Executive Directors:

- Mr Roger Corbett, AO - Independent Chairman
- Hon Ron Best - Independent Non-Executive Director
- Mr Patrick Blake - Independent Non-Executive Director
- Mr Frank Condella - Independent Non-Executive Director
- Ms Nancy Dolan - Independent Non-Executive Director
- Mr Phil Hodges - Independent Non-Executive Director (resigned 29 November 2018)
- Mr Bruce Mathieson - Independent Non-Executive Director
- Prof Bruce Robinson, AM - Independent Non-Executive Director
- Mr Ian Scholes - Independent Non-Executive Director

Executive Directors:

- Mr Scott Richards - Managing Director and Chief Executive Officer

Other executive KMP:

- Mr Nick Freeman - Group CFO and Company Secretary
- Mr Peter Paltoglou - Chief Development Officer and Head of M&A
- Dr Ilana Stancovski - Chief Scientific Officer and Head of European Market Development
- Mr Stefan Cross - President International Operations
- Ms Kate Rintoul - Executive Vice President and General Counsel
- Mr John Ross - President Mayne Pharma USA
- Ms Lisa Pendlebury - Vice President Investor Relations and Communications
- Mr Brant Schofield - Executive Vice President Speciality Brands Division (appointed 8 October 2018)

Executives with global responsibilities for business strategy and performance as well as guiding strategic allocation of resources and capital are considered KMP.

Previously all members of the Corporate Executive Committee (CEC) were considered KMP. In FY19 the number of executives participating in CEC increased considerably, the role of CEC changed and being a member of CEC was no longer considered an appropriate definition for KMP.

2. REMUNERATION GOVERNANCE

The Board of Directors has delegated the responsibility for determining and reviewing remuneration arrangements for the Directors, members of the KMP and the balance of the CEO's direct reports to the Remuneration and People Committee (RPC).

The RPC is made up of three Non-Executive Directors. The CEO, Group CFO and the Vice President, Group Human Resources attend meetings as required at the invitation of the Committee Chair.

The RPC assesses the appropriateness of the nature and amount of emoluments of such Directors and officers on a periodic basis by reference to relevant employment market conditions with the overall objective of ensuring maximum stakeholder benefit from the retention of a high-quality Board and executive team. Full responsibilities of the RPC are outlined in its Charter, which is available on the Mayne Pharma website.

To ensure the RPC is fully informed when making remuneration decisions it seeks advice from the Company's Vice President, Group Human Resources as well as specialist advice from external remuneration consultants. The RPC continued to engage independent remuneration consultants KPMG-3dc (formerly 3 degrees consulting) during the year.

The fees payable for FY19 to KPMG-3dc for remuneration advice were \$79,800 which included remuneration recommendations as defined under the *Corporations Act 2001*.

The RPC is satisfied that the advice received from KPMG-3dc was free from undue influence from the KMP to whom the recommendations may have related as KPMG-3dc were engaged by, and reported directly to, the Chair of the RPC.

Remuneration Report approval at the 2018 Annual General Meeting

The FY18 Remuneration Report received strong shareholder support at the 2018 AGM with a vote of 89% in favour. A resolution covering the issue of shares under the LTI share loan scheme to the CEO also received strong support with 89% of votes in favour.

3. REMUNERATION POLICY

In general, the Board links the nature and amount of KMP and other senior executives' emoluments to the Company's financial and operational performance. Given the nature of the industry in which the Company operates and the position it is in regarding the ongoing development of new products, the review of performance can also give regard to elements such as the scientific progress and commercialisation of the Company's projects, results of trials, progress with the development of relationships with sales and marketing partners, research institutions, and other collaborations.

Remuneration elements traditionally include fixed annual remuneration, short-term incentives and long-term incentives. The RPC have determined that shareholders' interests are best aligned with a remuneration structure that includes FAR and LTI elements only. Both FAR and total remuneration are benchmarked to ensure market competitiveness. However, as a result of this structure, a stronger proportion of total remuneration is in the form of LTI which is aligned to shareholders interests.

Remuneration paid to the Company's Directors and senior executives is determined with reference to the market level of remuneration for other listed development, pharmaceutical and manufacturing companies in Australia and the US. Specific roles are also benchmarked against similar roles in other listed companies with similar market capitalisation to Mayne Pharma. This assessment is undertaken with reference to published information provided by various executive search firms operating in the sector.

4. ELEMENTS OF KMP REMUNERATION

Remuneration packages contain the following key elements:

- Fixed remuneration
- Performance linked remuneration

Fixed remuneration

Managing Director and Officers

Fixed remuneration consists of a base remuneration package, which generally includes salary and employer contributions to superannuation funds.

Fixed remuneration levels for KMP and other senior executives are reviewed annually by the Board through a process that considers personal development, achievement of key performance objectives for the year, internal relativities, industry benchmarks wherever possible and CPI data.

In assessing fixed remuneration, the Board has considered the scale and complexity of the operations of Mayne Pharma, and the remuneration paid to comparable roles in other listed development, pharmaceutical and manufacturing companies in Australia and the US. Specific roles are also benchmarked against similar roles in other listed companies with similar market capitalisation to Mayne Pharma, both in Australia and the US.

The CEO's fixed remuneration is \$1,000,000. With the CEO's relocation to the US during the prior year, the CEO also receives a living away from home allowance, relocation support and other typical ex-pat benefits such as car lease, rental allowances, medical benefits and return airfares to Australia.

Performance-linked remuneration

Remuneration packages for KMP and senior executives do not include an entitlement to short-term incentives in the form of cash bonuses, but rather the entitlement to long-term incentives through the award of annual grants under the Executive Share Loan Scheme ('ESLS'). This incentive program ensures the key executives of Mayne Pharma are focussed on long-term growth of shareholder value.

LTI program

The ESLS allows the issue of shares to participants based on a percentage of fixed remuneration funded by a limited-recourse, interest free, five-year loan for the sole purpose of acquiring the shares. Issues are typically made annually to KMP and other senior executives who have foregone an STI entitlement. The shares are granted upfront based on the five-day volume weighted average price and remain restricted and subject to risk of forfeiture until the end of the vesting/performance period while the loan remains outstanding, with any unvested/unexercised shares lapsing 49 months after the first test date.

The number/proportion of ESLS that vest is based on the absolute Total Shareholder Return (TSR) over the period, 50% vesting if a TSR Compound Annual Growth (CAGR) of 5% (10% for pre- 1 July 2015 issues) is achieved, rising to 100% vesting for achievement of a TSR CAGR of 10% (15% for pre- 1 July 2015 issues). Vesting will occur on a straight-line basis for performance between these two points.

If the CAGR performance conditions are met, vesting occurs progressively and at continuously increasing hurdles. Vesting can occur over a period of 5 years (including six monthly in years 4 and 5) from the date of the grant, but the TSR vesting condition continues to compound in years 4 and 5.

The table below illustrates the required growth rates at a TSR CAGR of 5% pa which would represent 50% vesting:

	Year 1	Year 2	Year 3	Year 4	Year 5
Tranche 1 -20% of grant	TSR +5% from base year	TSR +10% from base year	TSR +16% from base year	TSR +22% from base year	TSR +28% from base year
Tranche 2 - 30% of grant	Not available for vesting	TSR +10% from base year	TSR +16% from base year	TSR +22% from base year	TSR +28% from base year
Tranche 3 - 50% of grant	Not available for vesting	Not available for vesting	TSR +16% from base year	TSR +22% from base year	TSR +28% from base year

The table below illustrates the required growth rates at a TSR CAGR of 10% pa which would represent 100% vesting:

	Year 1	Year 2	Year 3	Year 4	Year 5
Tranche 1 - 20% of grant	TSR +10% from base year	TSR +21% from base year	TSR +33% from base year	TSR +46% from base year	TSR +61% from base year
Tranche 2 - 30% of grant	Not available for vesting	TSR +21% from base year	TSR +33% from base year	TSR +46% from base year	TSR +61% from base year
Tranche 3 - 50% of grant	Not available for vesting	Not available for vesting	TSR +33% from base year	TSR +46% from base year	TSR +61% from base year

Vesting between 50% and 100% will occur on a straight-line basis for performance between these two points.

Following the end of the applicable vesting period, if the vesting conditions are met the ESLS shares will vest and the participant will then have until the end of the five-year term, plus one month, to repay the loan.

The Board has determined that the opportunity to vest over a 5-year period, noting that the TSR hurdles continue to compound and increase, is appropriate given the long-term nature of the development of products and inherent uncertainty regarding the timing of regulatory approvals for new products.

The Board also chose the absolute TSR growth targets to align executive reward with what the Board considers to be acceptable levels of return to Shareholders (ie. between 5% and 10% compound annual growth) over the performance period. The Board considered the use of a relative performance condition but does not consider that there are sufficient appropriate comparator pharmaceutical companies (ie. of similar size) listed in Australia. The Board took advice from KPMG-3dc on the appropriate TSR targets for the issues.

The Board has considered performance measures other than TSR and will continue to consider whether earnings or returns based measures are more appropriate for future grants.

Any dividends paid on shares while the ESLS are restricted are applied (on a notional after-tax basis) towards repaying the loan.

The base test dates for the ESLS issues made from 1 July 2015 to 31 December 2017 were set as 1 July each year. For earlier issues the testing dates were based on the anniversary of the grant date. Base test dates for grants after 31 December 2017 are either 1 March or 1 September to align with results announcements. These grants provide a rolling benefit to senior executives over the three-year period in the absence of a short-term incentive.

In the event of a Corporate Control Event, the TSR will be measured from the base test date to the date of the Corporate Control Event and LTI shares will vest immediately if the TSR hurdles are met. If any unvested shares do not automatically vest as a result of the Corporate Control Event, the Board may otherwise determine that some or all of those shares become vested shares.

Hedging of equity awards

The Company prohibits KMP from entering into arrangements to protect the value of unvested equity awards. The prohibition includes entering into contracts to hedge their exposure to options or ESLS shares awarded as part of their remuneration package.

5. EXECUTIVE KMP REMUNERATION

A) KMP STATUTORY REMUNERATION TABLES

The following table discloses executive KMP remuneration during the year ended 30 June 2019 as required by the Corporations Act:

	SHORT-TERM BENEFITS			POST-EMPLOYMENT BENEFITS	LONG TERM BENEFITS				TOTAL \$	TOTAL EXCL. CANCELLED LTI SHARES \$	PROPORTION RELATED TO PERFORMANCE %
	SALARY \$	ANNUAL LEAVE \$	OTHER BENEFITS ¹ \$	SUPER-ANNUATION \$	OTHER ² \$	OPTIONS \$	LTI SHARES \$	CANCELLED LTI SHARES \$			
Mr S Richards	979,469	75,342	368,863 ³	20,531	24,486	-	1,395,962	-	2,864,653	2,864,653	48.7
Mr N Freeman	548,793	43,576	-	25,166	9,434	-	441,835	-	1,068,804	1,068,804	41.3
Dr I Stancovski	553,983	-	-	-	-	-	400,170	-	954,153	954,153	41.9
Mr P Paltoglou	520,227	41,815	(2,193)	20,531	9,053	-	390,714	-	980,147	980,147	39.9
Mr S Cross	512,773	42,023	-	24,731	13,658	-	421,264	-	1,014,449	1,014,449	41.5
Ms K Rintoul	409,561	33,433	-	20,531	7,238	-	296,718	-	767,481	767,481	38.7
Mr J Ross	706,093	54,410	17,985	15,840	-	-	416,904	-	1,211,232	1,211,232	34.4
Mr L Pendlebury	260,845	21,544	-	20,531	4,664	-	149,043	-	456,627	456,627	32.6
Mr B Schofield	497,371	39,293	492,235 ⁴	8,603	-	-	257,174	-	1,294,676	1,294,676	19.9
Total	4,989,115	351,436	876,890	156,464	68,533	-	4,169,784	-	10,612,222	10,612,222	

- Other benefits include car lease payments, rental allowances, medical related payments, relocation and signing-on incentive.
- Other long-term benefits represent accruals for long service leave entitlements that may arise should the relevant key management personnel meet the eligibility requirements in the future.
- As Mr Richards relocated to the US during the prior year, he receives a living away from home allowance, relocation support and other typical ex-pat benefits such as car lease, rental allowances, medical benefits and return flights.
- Includes relocation and signing-on incentive paid at commencement totalling \$482,678.

The following table discloses executive KMP remuneration during the year ended 30 June 2018:

	SHORT-TERM BENEFITS			POST-EMPLOYMENT BENEFITS	LONG TERM BENEFITS				TOTAL \$	TOTAL EXCL. CANCELLED LTI SHARES \$	PROPORTION RELATED TO PERFORMANCE %
	SALARY \$	ANNUAL LEAVE \$	OTHER BENEFITS ⁵ \$	SUPER-ANNUATION \$	OTHER ⁶ \$	OPTIONS \$	LTI SHARES \$	CANCELLED LTI SHARES ⁸ \$			
Mr S Richards	857,488	67,687	201,751 ⁶	20,049	21,998	124,522	1,215,530	-	2,509,025	2,509,025	53.4
Mr N Freeman	510,659	42,307	-	23,429	9,159	-	277,735	-	863,289	863,289	32.2
Mr S Cross	484,531	40,799	-	25,199	13,260	25,191	364,159	342,210	1,295,349	953,139	56.5
Dr I Stancovski	483,237	19,654	-	-	(17,498)	-	332,056	279,816	1,097,265	817,449	55.8
Ms K Rintoul	378,204	32,459	-	20,049	7,027	539	247,037	246,829	932,144	685,315	53.0
Mr E Evans ⁷	61,986	35,952	2,753	3,918	-	-	(317,709) ⁷	-	(213,100)	(213,100)	n/a
Mr P Paltoglou	485,839	40,597	10,980	20,049	8,789	-	385,650	344,121	1,296,025	951,904	56.3
Ms L Pendlebury	251,004	20,916	-	20,049	4,528	-	140,598	142,683	579,778	437,095	48.9
Mr A Van Breugel ⁸	146,216	11,439	-	12,514	3,718	-	35,093	177,279	386,259	208,980	55.0
Mr J Ross	632,805	6,510	22,710	11,626	-	26,225	317,163	309,676	1,326,715	1,017,039	49.2
Total	4,291,969	318,320	253,194	266,220	50,981	176,477	2,997,312	1,842,614	11,194,199	9,351,585	

- Other benefits include car lease payments, rental allowances and medical related payments.
- Other long-term benefits represent accruals for long service leave entitlements that may arise should the relevant key management personnel meet the eligibility requirements in the future.
- As Mr Richards relocated to the US during the year, he receives a living away from home allowance, relocation support and other typical ex-pat benefits such as car lease, rental allowances, medical benefits and return flights.
- Mr Evans resigned 18 August 2017 and forfeited all non-vested LTI shares.
- Mr Van Breugel ceased to be a KMP effective 31 December 2017.
- Under the requirement of AASB2, the cancellation of the shares brought forward the future accounting expense which requires inclusion in this report. However, no KMP received a benefit from the cancellation of these shares.

Whilst the above KMP tables show statutory remuneration in accordance with accounting standards, the remuneration received by KMP was significantly lower as no employee exercised loan shares during FY19 and just one KMP exercised and sold 500,000 options granted in FY14 generating a benefit of \$142,650. Based on the 51c share price at 30 Jun 2019, no employee options or loan shares were in the money and could be exercised, which demonstrates the strong alignment of the LTI program with shareholders.

The challenges faced by Mayne Pharma over the last few years are reflected in the financial results of the company and ultimately in the remuneration outcomes for KMP. Since the introduction of the ESLS in FY15, no loan shares have been exercised by KMP and none were in the money at 30 June 2019.

B) EMPLOYMENT CONTRACTS

Remuneration and other key terms of employment for the CEO and other KMP are formalised in service agreements. The service agreements specify the components of remuneration, benefits, notice periods and termination provisions.

The table below provides details on the CEO's service agreement:

NAME	TERM OF AGREEMENT	BASE SALARY INCLUDING SUPERANNUATION ¹	NOTICE PERIOD	INCENTIVE ARRANGEMENTS	TERMINATION BENEFITS
Mr S Richards <i>Chief Executive Officer</i>	On-going commencing 13 February 2012	\$1,000,000	12 months	Entitlement to participate in LTI share plan. The value of the LTI is based on 200% of fixed remuneration. Minimum shareholding requirement 1,239,912 unrestricted shares.	Nil if for serious misconduct. Otherwise, up to 12 months' pay in lieu of notice. If employment is terminated within six months of a change of control, entitled to a payment equal to 12 months' pay.

- Base salary quoted is for a 12-month period and is current and is reviewed annually by the Remuneration and People Committee. Note as Mr Richards relocated to the US, he also receives living away from home, relocation assistance and other typical expat benefits.

Other executive KMP are subject to ongoing service agreements with the majority of notice periods being 6 months. Other KMP participate in the ESLS receiving an annual allocation of shares under the plan. ESLS participation is based on an LTI value of between 80% and 110% of fixed remuneration. These executives do not participate in the STI plan.

To align the executive KMP interests with shareholder interests, all executive KMP are required to build and hold a specified minimum shareholding in the Company over time. Executives' minimum shareholding requirement is based on their LTI participation rate, the Mayne Pharma share price and their salary when they were first granted LTI shares.

6. NON-EXECUTIVE DIRECTORS' REMUNERATION

Total remuneration for Non-Executive Directors (NED) is determined by resolution of shareholders. The maximum available aggregate cash remuneration approved for Non-Executive Directors at the 2018 Annual General Meeting is \$1,800,000. Non-Executive Directors do not receive retirement benefits other than a superannuation guarantee contribution required by government regulation for Australian Directors, which is currently 9.5% of their fees, except where a Non-Executive Director elects to have their fees paid as contributions to a superannuation fund.

NED fee arrangements are designed to appropriately compensate suitably qualified directors with appropriate experience and expertise to discharge their responsibilities. In FY19, the Board had two committees for which fees were payable. The Board reviews the fees on an annual basis with reference to market rates in Australia and the US.

Current NED Fees are as follows, with Australian-based Directors receiving 9.5% superannuation in addition to these fees (US-based Directors receive an additional loading equivalent to this superannuation amount):

	Board	Audit and Risk Committee	Science, Technology and Medicine Committee	Remuneration and People Committee	Nominations Committee
Australian Based Chair	A\$250,000	A\$20,000	A\$15,000	Nil	Nil
Australian Based Director	A\$120,000	A\$10,000	A\$8,000	Nil	Nil
US Based Director	US\$120,000	US\$10,000	US\$8,000	Nil	Nil

During the prior year, the Board introduced a new minimum shareholding policy. The policy outlines an expectation that Non-Executive Directors will accumulate at least 1x base remuneration in Mayne Pharma shares within the first three years following their appointment. The Board believes this will ensure close alignment between Non-Executive Directors and shareholders over the long term, particularly for new appointees.

Non-Executive Directors may provide specific consulting advice to the Group upon direction from the Board. Remuneration for this work is made at market rates. No such consulting advice was provided to the Company during the year or the prior year.

	YEAR	DIRECTORS' FEES \$	OTHER BENEFITS ¹ \$	SUPER-ANNUATION \$	TOTAL \$
Mr R Corbett	2019	250,000	30,000	23,750	303,750
	2018	250,000	15,000	23,750	288,750
Hon R Best	2019	117,600	-	24,750	142,350
	2018	117,600	-	24,750	142,350
Mr P Blake	2019	156,973	-	-	156,973
	2018	-	-	-	-
Mr F Condella	2019	156,973	-	-	156,973
	2018	10,950	-	-	10,950
Ms N Dolan ²	2019	130,000	-	12,350	142,350
	2018	125,112	-	25,450	150,562
Mr B Mathieson ²	2019	120,000	-	11,400	131,400
	2018	112,500	-	10,688	123,188
Mr I Scholes	2019	140,000	-	13,300	153,300
	2018	140,000	-	13,300	153,300
Mr P Hodges	2019	66,240	-	-	66,240
	2018	120,950	-	-	120,950
Prof B Robinson	2019	122,500	-	11,638	134,138
	2018	120,000	-	11,400	131,400
Totals	2019	1,260,286	30,000	97,188	1,387,474
	2018	997,112	15,000	109,338	1,121,450

- Other benefits include serviced office facilities for the Chairman.
- Ms Dolan and Mr Mathieson's fees were adjusted during FY18 to reflect their involvement in the Audit and Risk committee. Ms Dolan replaced Mr Mathieson on this committee from 1 October 2016.

7. VALUE OF EQUITY INSTRUMENTS GRANTED TO KMP

Options awarded, vested, exercised and lapsed

The number and value of outstanding options granted to, exercised by, or forfeited by KMP in the current period is set out below:

	GRANT DATE	NUMBER HELD AT 1 JULY 2018	NUMBER GRANTED DURING YEAR	NUMBER EXERCISED DURING YEAR	NUMBER LAPSED OR FORFEITED DURING THE YEAR	NUMBER HELD AT 30 JUNE 2019	NUMBER VESTED AT 30 JUNE 2019	VALUE OF OPTIONS AT GRANT DATE \$ ¹	VALUE OF OPTIONS INCLUDED IN COMPENSATION FOR THE YEAR \$
Year ended 30 June 2019									
Mr S Cross	21 Apr 14	1,000,000	-	(500,000)	(500,000)	-	-	391,710	-
Mr J Ross	1 May 14	1,000,000	-	-	(500,000)	500,000	500,000	380,420	-
		2,000,000	-	(500,000)	(1,000,000)	500,000	500,000	772,130	-

- The value at grant date has been adjusted to include the value of modifications which occurred in prior periods.

The number and value of outstanding options granted to, exercised by, or forfeited by KMP in the prior period is set out below:

	GRANT DATE	NUMBER HELD AT 1 JULY 2017	NUMBER GRANTED DURING YEAR	NUMBER EXERCISED DURING YEAR	NUMBER LAPSED DURING THE YEAR	NUMBER HELD AT 30 JUNE 2018	NUMBER VESTED AT 30 JUNE 2018	VALUE OF OPTIONS AT GRANT DATE \$ ¹	VALUE OF OPTIONS INCLUDED IN COMPENSATION FOR THE YEAR \$
Year ended 30 June 2018									
Mr S Cross	25 Jan 13	800,000	-	(800,000)	-	-	-	172,960	-
Mr S Cross	21 Apr 14	1,000,000	-	-	-	1,000,000	500,000	391,710	25,191
Mr J Ross	1 May 14	1,000,000	-	-	-	1,000,000	500,000	380,420	26,225
		2,800,000	-	(800,000)	-	2,000,000	1,000,000	945,090	51,416

- The value at grant date has been adjusted to include the value of modifications which occurred in prior periods.

No other KMP held options during FY19 or FY18 and no options were granted or modified during the period.

LTI Shares

As noted above, under the LTI program, eligible KMP (and other select senior management) are invited to acquire shares in the Company funded by a limited-recourse loan from the Group. The shares are issued at market value at the time of the grant (based on 5-day VWAP). Although the shares are acquired under the plan for legal and taxation purposes, Australian Accounting Standards require the shares be treated as options for accounting purposes. As a result, the amounts receivable from KMP in relation to these loans are not recognised in the financial statements.

ESLS awarded, vested, exercised, cancelled and lapsed

The number and value of outstanding ESLS granted to KMP is set out below:

	GRANT DATE	EXPIRY DATE	EXERCISE PRICE/ 5 DAY VWAP AT GRANT DATE	NUMBER HELD AT 1 JULY 2018	NUMBER GRANTED DURING YEAR	NUMBER EXERCISED DURING YEAR	NUMBER LAPSED OR CANCELLED DURING THE YEAR	NUMBER HELD AT 30 JUNE 2019	NUMBER VESTED AT 30 JUNE 2019	VALUE OF OPTIONS AT GRANT DATE \$	VALUE OF OPTIONS INCLUDED IN COMPENSATION FOR THE YEAR \$
Year ended 30 June 2019											
Mr S Richards	4 Dec 2014	4 Jan 2020	\$0.6815	3,823,529	-	-	-	3,823,529	2,676,470	845,000	169,000
	4 Dec 2015	31 Aug 2020	\$1.2300	2,553,496	-	-	-	2,553,496	510,699	1,237,169	-
	6 Dec 2016	31 Jul 2021	\$1.5760	2,242,005	-	-	-	2,242,005	-	949,815	340,626
	7 Dec 2017	31 Jul 2022	\$0.6169	6,608,851	-	-	-	6,608,851	1,321,770	1,311,196	513,534
	6 Dec 2018	1 Oct 2023	\$0.9696	-	6,229,373 ¹	-	-	6,229,373	-	1,871,927	372,802
Dr I Stancovski	2 Feb 2015	2 Mar 2020	\$0.6163	833,003	-	-	-	833,003	708,053	210,000	42,000
	3 Aug 2015	31 Aug 2020	\$1.1000	791,789	-	-	-	791,789	158,358	350,050	21,798
	3 Jul 2017	31 Jul 2022	\$1.1307	1,169,879	-	-	-	1,169,879	-	377,169	123,726
	28 Sep 2017	31 Jul 2022	\$0.6631	332,474	-	-	-	332,474	66,495	70,750	29,225
	23 Mar 2018	31 Mar 2023	\$0.7620	2,025,258	-	-	-	2,025,258	-	550,263	183,421
Mr P Paltoglou	24 Aug 2015	31 Aug 2020	\$1.1300	2,231,344	-	-	-	2,231,344	446,269	633,032	38,334
	3 Jul 2017	31 Jul 2022	\$1.1307	1,278,871	-	-	-	1,278,871	-	412,308	135,253
	28 Sep 2017	31 Jul 2022	\$0.6631	314,989	-	-	-	314,989	62,998	67,030	27,689
	23 Mar 2018	31 Mar 2023	\$0.7620	2,091,695	-	-	-	2,091,695	-	568,314	189,438
Mr N Freeman	3 Jul 2017	31 Jul 2022	\$1.1307	2,124,415	-	-	-	2,124,415	-	684,911	224,677
	23 Mar 2018	31 Mar 2023	\$0.7620	2,397,769	-	-	-	2,397,769	-	651,474	217,158
Mr S Cross	3 Aug 2015	31 Aug 2020	\$1.1000	1,257,153	-	-	-	1,257,153	251,431	555,787	34,609
	3 Jul 2017	31 Jul 2022	\$1.1307	1,297,861	-	-	-	1,297,861	-	418,430	137,261
	28 Sep 2017	31 Jul 2022	\$0.6631	295,077	-	-	-	295,077	59,015	62,792	20,623
	23 Mar 2018	31 Mar 2023	\$0.7620	2,102,110	-	-	-	2,102,110	-	571,143	190,381
	1 Oct 2018	30 Sep 2023	\$1.2752	-	331,981 ²	-	-	331,981	-	156,399	38,389
Ms K Rintoul	3 Aug 2015	31 Aug 2020	\$1.1000	666,533	-	-	-	666,533	133,307	294,674	18,350
	3 Jul 2017	31 Jul 2022	\$1.1307	1,031,965	-	-	-	1,031,965	-	332,705	109,140
	28 Sep 2017	31 Jul 2022	\$0.6631	254,176	-	-	-	254,176	50,835	54,089	17,765
	23 Mar 2018	31 Mar 2023	\$0.7620	1,672,400	-	-	-	1,672,400	-	454,391	151,464
Mr J Ross	3 Aug 2015	31 Aug 2020	\$1.1000	908,131	-	-	-	908,131	181,626	401,485	25,001
	3 Jul 2017	31 Jul 2022	\$1.1307	1,197,845	-	-	-	1,197,845	-	386,185	126,684
	28 Sep 2017	31 Jul 2022	\$0.6631	442,778	-	-	-	442,778	88,556	94,223	30,947
	23 Mar 2018	31 Mar 2023	\$0.7620	2,162,862	-	-	-	2,162,862	-	587,650	195,883
	1 Oct 2018	30 Sep 2023	\$1.2752	-	331,981 ²	-	-	331,981	-	156,399	38,389
Ms L Pendlebury	11 Nov 2015	31 Aug 2020	\$1.0460	524,070	-	-	-	524,070	104,814	200,771	12,985
	3 Jul 2017	31 Jul 2022	\$1.1307	530,259	-	-	-	530,259	-	170,955	56,080
	28 Sep 2017	31 Jul 2022	\$0.6631	27,126	-	-	-	27,126	5,425	5,772	1,896
	23 Mar 2018	31 Mar 2023	\$0.7620	862,151	-	-	-	862,151	-	234,246	78,082
Mr B Schofield	8 Oct 2018	30 Sep 2023	\$1.2909	-	2,489,627 ³	-	-	2,489,627	-	1,041,909	257,174
				46,051,864	9,382,962	-	-	55,434,826	6,826,121	16,970,415	4,169,783

1. The average value of the options granted during the year was \$0.30 each.
2. The average value of the options granted during the year was \$0.44 each.
3. The average value of the options granted during the year was \$0.42 each.

8. OPTIONS AND SHARES GRANTED SUBSEQUENT TO REPORTING DATE

No options or loan shares were issued to KMP subsequent to report date.

9. SHARES ISSUED ON EXERCISE OF OPTIONS BY KMP

The number of shares issued to KMP on the exercise of options during the year ended 30 June 2019 was as follows.

	SHARES ISSUED NUMBER	PAID PER SHARE \$	UNPAID PER SHARE \$
30 June 2019			
Mr S Cross	500,000	0.6647	-
Total	500,000		-

10. SHARES HELD BY KMP

Movements in shares

The movement during FY18 and FY19 in the number of ordinary shares in the Company held, directly, indirectly or beneficially, by each KMP including their related parties at reporting date, is as follows:

	HELD AT 30 JUNE 2017 NUMBER	RECEIVED DURING FY18 ON EXERCISE OF OPTIONS AND / OR LTI SHARES GRANTED NUMBER	CANCELLED DURING FY18 NUMBER	OTHER CHANGES DURING FY18 NUMBER	HELD AT 30 JUNE 2018 NUMBER	RECEIVED DURING FY19 ON EXERCISE OF OPTIONS AND / OR LTI SHARES GRANTED NUMBER	OTHER CHANGES DURING FY19 NUMBER	HELD AT 30 JUNE 2019 NUMBER
Directors								
Mr R Corbett	10,440,569	-	-	-	10,440,569	-	-	10,440,569
Mr S Richards	25,487,594	6,608,851	-	(10,883,195)	21,213,250	6,229,373	-	27,442,623
Hon R Best	1,587,217	-	-	-	1,587,217	-	-	1,587,217
Mr P Blake	-	-	-	-	-	-	-	-
Mr F Condella	-	-	-	-	-	-	181,835	181,835
Ms N Dolan	74,500	-	-	-	74,500	-	27,272	101,772
Mr B Mathieson	90,777,583	-	-	8,000,000	98,777,583	-	-	98,777,583
Mr I Scholes	2,158,636	-	-	-	2,158,636	-	-	2,158,636
Mr P Hodges	6,739,554	-	-	-	6,739,554	-	-	6,739,554
Prof B Robinson	634,895	-	-	-	634,895	-	-	634,895
	137,900,548	6,608,851	-	(2,883,195)	141,626,204	6,229,373	209,107	148,064,684
Other KMP								
Mr N Freeman	-	4,522,184	-	76,071	4,598,255	-	(76,071)	4,522,184
Dr I Stancovski	2,464,207	3,527,611	(584,979)	-	5,406,839	-	-	5,406,839
Mr P Paltoglou	4,906,116	3,685,555	(719,413)	(1,293,510)	6,578,748	-	-	6,578,748
Mr S Cross	2,855,286	4,495,048	(715,418)	(800,000)	5,834,916	831,981	(850,000)	5,816,897
Ms K Rintoul	1,182,550	2,958,541	(516,017)	-	3,625,074	-	-	3,625,074
Mr J Ross	1,692,917	3,803,485	(684,783)	-	4,811,619	331,981	-	5,143,600
Ms L Pendlebury	1,461,057	1,419,536	(298,291)	107,292	2,689,594	-	-	2,689,594
Mr B Schofield	-	-	-	-	-	2,489,627	-	2,489,627
	14,562,133	24,411,960	(3,518,901)	(1,910,147)	33,545,045	3,653,589	(926,071)	36,272,563
	152,462,681	31,020,811	(3,518,901)	(4,793,342)	175,171,249	9,882,962	(716,964)	184,337,247

11. GROUP PERFORMANCE

In considering the Group's performance, the Board has regard to a broad range of factors primarily related to financial and operational performance, scientific progress and commercialisation of the Company's projects, results of trials, relationship building with sales and marketing partners, research institutions, and collaborations.

The following table outlines key statistics reported by the Company over the last five years to 30 June 2019:

	2019	2018	2017	2016	2015
Total revenue (\$000)	525,208	530,313	572,595	267,280	141,420
NPAT (\$000) attributable to Mayne Pharma shareholders	(280,866)	(133,984)	88,562	37,355	7,759
Basic EPS (cents)	(19.04)	(9.16)	6.18	4.77	1.18
Share price (30 June)	\$0.510	\$0.870	\$1.085	\$1.905	\$0.985
Dividends per share (cents)	-	-	-	-	-

As part of the Board's commitment to align remuneration with Company performance, employee performance is reviewed annually against agreed performance objectives set prior to the commencement of the financial year. The Company's performance review system involves employees completing a self-assessment template, as well as their manager completing an assessment document. These assessments form the basis of a performance review discussion between each employee and their manager.

The Board (through the RPC) agrees objectives for the evaluation of the CEO. The performance of the CEO against the agreed objectives is reviewed by the Chairman on behalf of the Board. The performance of the other KMP and other senior executives is reviewed by the CEO and reported to, and discussed by, the Board. Performance reviews take place shortly after the end of the financial year.

As outlined in this report, the Company has implemented a broader based LTI program for senior management. This plan places a significant percentage of remuneration at risk and more closely aligns employee remuneration with the earnings growth of the Company.

The Company has 145 senior members or 15% of staff participating in long term incentive schemes, either through previous option issues, or more recently through the share loan scheme, including 14 senior executives who have agreed to forgo STI entitlements. The Board considers this a strong indication of the alignment of the shareholders' and employees' interests.

The challenges faced by Mayne Pharma over the last few years are reflected in the financial results of the company and ultimately in the remuneration outcomes for KMP. Since the introduction of the ESLS in FY15, which superseded the option scheme as the new LTI, less than 7% of loan shares have vested and only 84,999 loan shares have been exercised. The total cash benefit realised to all employees from the share loan scheme for the period FY15 to FY19 has been \$80,749.

Based on the 51c share price at 30 June 2019, no employee options or loan shares were in the money and could be exercised, which demonstrates the strong alignment of the LTI program with shareholders.

This Directors' Report is signed in accordance with a resolution of the Directors.

Dated at Melbourne, Australia this 23rd day of August 2019.

A handwritten signature in black ink, appearing to read 'S Richards', with a long horizontal flourish extending to the right.

Mr Scott Richards
Managing Director and CEO



Ernst & Young
8 Exhibition Street
Melbourne VIC 3000 Australia
GPO Box 67 Melbourne VIC 3001

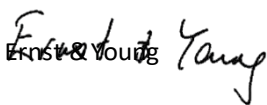
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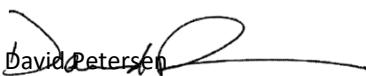
Auditor's Independence Declaration to the Directors of Mayne Pharma Group Limited

As lead auditor of the audit of the financial report of Mayne Pharma Group Limited for the financial year ended 30 June 2019, I declare to the best of my knowledge and belief, there have been:

- a) no contraventions of the auditor independence requirements of the *Corporations Act 2001* in relation to the audit; and
- b) no contraventions of any applicable code of professional conduct in relation to the audit.

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


Ernst & Young


David Petersen
Partner
23 August 2019

CORPORATE GOVERNANCE WEBSITE

Important information relating to the Company's corporate governance policies and practices are set out on the Company's website at <http://www.maynepharma.com/investor-relations/corporate-governance>.

The Company has adopted the ASX Corporate Governance Council 3rd Edition Corporate Governance Principles and Recommendations. The recommendations allow companies to publish Corporate Governance information on their websites rather than include the information in the Annual Report.

The following documents are available on the Mayne Pharma website:

- Corporate Governance Statement;
- Board Charter;
- Audit & Risk Committee, Remuneration & People Committee, Nomination Committee and Science, Technology & Medical Committee Charters;
- Business Code of Conduct;
- Communications Policy;
- Continuous Disclosure Policy;
- Risk Management Framework;
- Workplace Gender Equality Agency Annual Compliance Report; and
- Securities Trading Policy.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

For the year ended 30 June 2019

	NOTE	CONSOLIDATED	
		2019 \$'000	2018 \$'000
Revenue from contracts with customers			
Sale of goods		440,050	456,001
Services revenue		82,746	73,140
License fee revenue		1,162	-
Royalties revenue		1,250	1,172
Revenue	2	525,208	530,313
Cost of sales	6	(235,273)	(273,764)
Gross profit		289,935	256,549
Interest revenue		1,016	112
Other income	4	1,715	2,579
Research and development expenses		(28,534)	(15,477)
Marketing and distribution expenses		(76,667)	(62,790)
Administration expenses and other expenses	6	(171,947)	(146,087)
Impairments	14	(351,716)	(184,374)
Finance expenses	6	(17,519)	(17,307)
Profit before income tax		(353,717)	(166,787)
Income tax credit / (expense)	7	69,966	32,530
Net profit from continuing operations after income tax		(283,751)	(134,257)
Attributable to:			
Equity holders of the Parent		(280,866)	(133,984)
Non-controlling interests		(2,885)	(273)
		(283,751)	(134,257)
Other comprehensive income/(loss) for the period, net of tax			
<u>Items that may be reclassified to profit or loss in future periods</u>			
Unrealised gain / (loss) on cash flow hedges		(7,184)	5,332
Income tax effect		-	-
Exchange differences on translation		58,668	36,287
Income tax effect		(5,972)	-
<u>Items that will not be reclassified to profit or loss in future periods</u>			
Exchange differences on translation		501	380
Income tax effect		-	-
Total comprehensive income for the period		(237,738)	(92,258)
Attributable to:			
Equity holders of the Parent		(235,354)	(92,365)
Non-controlling interests		(2,384)	107
		(237,738)	(92,258)
Basic earnings per share	8	(19.04) cents	(9.16) cents
Diluted earnings per share	8	(19.04) cents	(9.16) cents

This statement is to be read in conjunction with the accompanying notes.

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

As at 30 June 2019

	NOTE	CONSOLIDATED	
		2019 \$'000	2018 \$'000
Current assets			
Cash and cash equivalents	22	89,004	87,312
Trade and other receivables	9	256,580	252,715
Inventories	10	100,348	82,156
Income tax receivable		523	22,206
Other financial assets	11	962	15,428
Other current assets	12	24,530	20,950
Total current assets		471,946	480,767
Non-current assets			
Property, plant and equipment	13	236,034	230,051
Deferred tax assets	7	130,721	65,164
Intangible assets and goodwill	14	797,632	1,054,526
Total non-current assets		1,164,387	1,349,741
Total assets		1,636,333	1,830,508
Current liabilities			
Trade and other payables	15	129,942	152,561
Interest-bearing loans and borrowings	16	50,881	58
Other financial liabilities	17	13,922	12,477
Provisions	18	16,585	15,629
Total current liabilities		211,329	180,725
Non-current liabilities			
Interest-bearing loans and borrowings	16	318,501	374,132
Other financial liabilities	17	59,953	5,350
Deferred tax liabilities	7	31,360	34,030
Provisions	18	1,116	1,113
Total non-current liabilities		410,929	414,625
Total liabilities		622,258	595,351
Net assets		1,014,075	1,235,157
Equity			
Contributed equity	19	1,140,008	1,131,761
Reserves	20	125,099	71,178
Retained earnings	21	(257,341)	23,525
Equity attributable to equity holders of the Parent		1,007,766	1,226,464
Non-controlling interests		6,309	8,693
Total equity		1,014,075	1,235,157

This statement is to be read in conjunction with the accompanying notes.

CONSOLIDATED STATEMENT OF CASH FLOWS

For the year ended 30 June 2019

	NOTE	CONSOLIDATED	
		2019 \$'000	2018 \$'000
Cash flows from operating activities			
Receipts from customers		714,170	646,011
Payments to suppliers and employees		(586,558)	(483,443)
Interest received		1,016	112
Interest paid		(14,565)	(15,176)
Tax paid		-	(10,731)
Tax received		21,025	2,764
Net operating cash flows before research and non-capitalised development expenditure, set-up and transaction costs		135,088	139,537
Payments for research and non-capitalised development expenditure		(25,805)	(13,878)
Restructuring costs paid		-	(3,489)
Drug pricing investigations and related litigation costs		(2,677)	(672)
Net cash flows from operating activities	22	106,606	121,498
Cash flows from investing activities			
Payments for property, plant and equipment		(11,913)	(54,181)
Payments for intangible assets		(48,248)	(7,371)
Payments for capitalised development costs		(21,759)	(32,785)
Investment in subsidiary		-	(108)
Acquisition of HPPI warrants		(475)	(486)
Earn-out and deferred settlement payments		(9,290)	(23,417)
Net cash flows used in investing activities		(91,686)	(118,348)
Cash flows from financing activities			
Proceeds from issues of shares		7,053	1,526
Equity contributions from non-controlling interests		-	(65)
Repayment of borrowings		(62,549)	(118)
Proceeds from borrowings (net of fees)		39,944	18,835
Net cash flows from financing activities		(15,552)	20,178
Net increase / (decrease) in cash and cash equivalents		(632)	23,328
Cash and cash equivalents at the beginning of the period		87,312	63,027
Effect of exchange rate fluctuations on cash held		2,324	957
Cash at the end of the period	22	89,004	87,312

This statement is to be read in conjunction with the accompanying notes.

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

For the year ended 30 June 2019

	CONTRIBUTED EQUITY \$'000	SHARE-BASED PAYMENTS RESERVE \$'000	FOREIGN CURRENCY TRANSLATION RESERVE \$'000	CASH FLOW HEDGE RESERVE \$'000	OTHER RESERVE \$'000	RETAINED EARNINGS \$'000	TOTAL \$'000	NON- CONTROLLING INTERESTS \$'000	TOTAL EQUITY \$'000
Balance at 1 July 2018	1,131,761	20,813	47,339	6,747	(3,721)	23,525	1,226,464	8,693	1,235,157
Profit/(loss) for the period	-	-	-	-	-	(280,866)	(280,866)	(2,885)	(283,751)
Other comprehensive income	-	-	-	-	-	-	-	-	-
Cash flow hedge	-	-	-	(7,184)	-	-	(7,184)	-	(7,184)
Foreign exchange differences (net of tax)	-	-	52,696	-	-	-	52,696	501	53,197
Total comprehensive income for the period	-	-	52,696	(7,184)	-	(280,866)	(235,354)	(2,384)	(237,738)
Transactions with owners in their capacity as owners									
Shares issued	7,081	-	-	-	-	-	7,081	-	7,081
Share issue costs (net of tax)	(31)	-	-	-	-	-	(31)	-	(31)
Change equity investment in subsidiary	-	-	-	-	578	-	578	-	578
Tax effect of employee share options	24	-	-	-	-	-	24	-	24
Share-based payments	-	9,004	-	-	-	-	9,004	-	9,004
Share options exercised	1,173	(1,173)	-	-	-	-	-	-	-
Transfer to retained earnings – lapsed and cancelled employee LTI shares	-	-	-	-	-	-	-	-	-
Balance at 30 June 2019	1,140,008	28,644	100,035	(437)	(3,143)	(257,341)	1,007,766	6,309	1,014,075
Balance at 1 July 2017	1,130,404	14,890	11,052	1,415	(4,020)	150,097	1,303,838	8,586	1,312,424
Profit/(loss) for the period	-	-	-	-	-	(133,984)	(133,984)	(273)	(134,257)
Other comprehensive income	-	-	-	-	-	-	-	-	-
Cash flow hedge	-	-	-	5,332	-	-	5,332	-	5,332
Foreign exchange differences	-	-	36,287	-	-	-	36,287	380	36,667
Total comprehensive income for the period	-	-	36,287	5,332	-	(133,984)	(92,365)	107	(92,258)
Transactions with owners in their capacity as owners									
Shares issued	1,529	-	-	-	-	-	1,529	-	1,529
Share issue costs (net of tax)	(2)	-	-	-	-	-	(2)	-	(2)
Change equity investment in subsidiary	-	-	-	-	299	-	299	-	299
Tax effect of employee share options	(1,324)	-	-	-	-	-	(1,324)	-	(1,324)
Share-based payments	-	14,490	-	-	-	-	14,490	-	14,490
Share options exercised	1,155	(1,155)	-	-	-	-	-	-	-
Transfer to retained earnings – lapsed and cancelled employee LTI shares	-	(7,412)	-	-	-	7,412	-	-	-
Balance at 30 June 2018	1,131,761	20,813	47,339	6,747	(3,721)	23,525	1,226,464	8,693	1,235,157

This statement is to be read in conjunction with the accompanying notes.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

For the year ended 30 June 2019

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NOTE 1 – ABOUT THIS REPORT

Mayne Pharma Group Limited is a company limited by shares incorporated and domiciled in Australia, whose shares are publicly traded on the Australian Securities Exchange. The financial report for the year ended 30 June 2019 was authorised for issue by the Directors on 23 August 2019.

The nature of the operations and principal activities of the Group are described in the Directors' Report.

A. Basis of preparation

These financial statements are general purpose financial statements which have been prepared for a "for-profit" enterprise and in accordance with the requirements of the Corporations Act 2001, Australian Accounting Standards and other authoritative pronouncements of the Australian Accounting Standards Board. The financial report has been prepared on a historical cost basis except for certain financial instruments which have been measured at fair value.

The financial report complies with Australian Accounting Standards as issued by the Australian Accounting Standards Board and International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board.

The financial report is presented in Australian dollars and rounded to the nearest thousand dollars (\$'000) unless otherwise stated.

B. Basis of consolidation

The consolidated financial statements comprise the financial statements of the Group and its subsidiaries as at 30 June 2019. Control is achieved when the Group is exposed, or has rights, to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee. Specifically, the Group controls an investee if and only if the Group has:

- Power over the investee (i.e. existing rights that give it the current ability to direct the relevant activities of the investee);
- Exposure, or rights, to variable returns from its involvement with the investee; and
- The ability to use its power over the investee to affect its returns.

When the Group has less than a majority of the voting or similar rights of an investee, the Group considers all relevant facts and circumstances in assessing whether it has power over an investee, including:

- The contractual arrangement with the other vote holders of the investee;
- Rights arising from other contractual arrangements; and
- The Group's voting rights and potential voting rights.

The Group re-assesses if it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control. Consolidation of a subsidiary begins when the Group obtains control over the subsidiary and ceases when the Group loses control of the subsidiary. Assets, liabilities, income and expenses of a subsidiary acquired or disposed of during the year are included in the statement of comprehensive income from the date the Group gains control until the date the Group ceases to control the subsidiary.

Profit or loss and each component of other comprehensive income (OCI) are attributed to the equity holders of the parent of the Group and to the non-controlling interests, even if this results in the non-controlling interests having a deficit balance. When necessary, adjustments are made to the financial statements of subsidiaries to bring their accounting policies into line with the Group's accounting policies. All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

A change in the ownership interest of a subsidiary, without a loss of control, is accounted for as an equity transaction. If the Group loses control over a subsidiary, it:

- De-recognises the assets (including goodwill) and liabilities of the subsidiary;
- De-recognises the carrying amount of any non-controlling interests;
- De-recognises the cumulative translation differences recorded in equity;
- Recognises the fair value of the consideration received;
- Recognises the fair value of any investment retained;
- Recognises any surplus or deficit in profit or loss; and
- Reclassifies the parent's share of components previously recognised in OCI to profit or loss or retained earnings, as appropriate, as would be required if the Group had directly disposed of the related assets or liabilities.

C. Foreign currency

The Group's consolidated financial statements are presented in Australian dollars, which is also the parent's functional currency. The Group determines the functional currency for each entity and items included in the financial statements of each entity are measured using that functional currency. The functional currency for the US subsidiaries is US dollars.

On consolidation, the assets and liabilities of foreign operations are translated into Australian dollars at the rate of exchange prevailing at the reporting date and their income statements are translated at exchange rates prevailing at the dates of the transactions. The exchange differences arising on translation for consolidation are recognised in equity through Other Comprehensive Income. On disposal of a foreign operation, the component of equity relating to that foreign operation is reclassified to profit or loss as part of the gain or loss on sale.

Transactions in foreign currencies are initially recorded by the Group's entities at their respective functional currency spot rates at the date the transaction first qualifies for recognition.

Monetary assets and liabilities denominated in foreign currencies are translated at the functional currency spot rates of exchange at the reporting date.

Differences arising on settlement or translation of monetary items are recognised in profit or loss except monetary items that are designated as part of the hedge of the Group's net investment of a foreign operation. These are recognised in other comprehensive income until the net investment is disposed of, at which time, the cumulative amount is reclassified to profit or loss. Tax charges and credits attributable to exchange differences on those monetary items are also recorded in other comprehensive income.

In substance, the Group's net investment in a foreign operation includes loans advanced by the parent entity to the foreign operation where settlement of which is neither planned nor likely to occur within the foreseeable future. Exchange differences arising on such monetary items that form part of a reporting entity's net investment in a foreign operation are recognised in profit or loss in the separate financial statements of the reporting entity. In the Group's financial statements which include the foreign operation and the reporting entity, such exchange differences are recognised initially in other comprehensive income and reclassified from equity to profit or loss on disposal of the net investment.

Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rates at the dates of the initial transactions. Non-monetary items measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value is determined. The gain or loss arising on translation of non-monetary items measured at fair value is treated in line with the recognition of gain or loss on change in fair value of the item (i.e. translation differences on items whose fair value gain or loss is recognised in other comprehensive income or profit or loss are also recognised in other comprehensive income or profit or loss, respectively).

Any goodwill arising on the acquisition of a foreign operation and any fair value adjustments to the carrying amounts of assets and liabilities arising on the acquisition are treated as assets and liabilities of the foreign operation and translated at the spot rate of exchange at the reporting date.

D. Other accounting policies

Significant accounting policies that outline the measurement basis used and are relevant to the understanding of the financial statements are provided throughout the notes to the financial statements.

E. Key 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. Material judgements and estimates are found in the following notes:

Note	Significant judgements and estimates
• Note 2 - Reporting Segment information	Revenue recognition
• Note 7 - Income tax	Recognition of deferred tax assets and liabilities
• Note 9 - Receivables	Customer charge-backs and discounts
• Note 10 - Inventories	Obsolescence and net realisable value assessment
• Note 14 - Intangible assets	Development expenditure capitalisation, Impairment and assessment of useful lives
• Note 15 - Trade and Other Payables	Customer rebates, returns and loyalty programs
• Note 17 - Other Financial Liabilities	Fair value of liabilities
• Note 18 - Provisions	Best estimates of expenditure to be settled
• Note 26 - Share-Based Payments	Fair value of equity instruments

F. Significant changes in the current reporting period

From 1 July 2018 the Group has adopted the relevant standards and interpretations mandatory for annual reports beginning on or after 1 July 2018. Adoption of the standards and interpretations had no material effect on the financial position or performance of the Group.

The accounting policies and methods of computation are the same as those adopted in the prior annual financial report except for the Group has applied AASB 15 Revenue from contracts with customers with effect from 1 July 2018.

AASB 15 establishes a five-step model to account for revenue arising from contracts with customers and requires that revenue be recognised at an amount that reflects the consideration to which an entity expects to be entitled in exchange for transferring goods or services to a customer.

AASB 15 requires entities to exercise judgement, taking into consideration all the relevant facts and circumstances when applying each step of the model to contracts with their customers. The standard also specifies the accounting for the incremental costs of obtaining a contract and the costs directly related to fulfilling a contract. In addition, the standard requires extensive disclosures.

Mayne Pharma adopted AASB 15 applying the modified retrospective approach. This method requires the recognition of the cumulative effect of initially applying AASB 15 to retained earnings and not to restate prior years. AASB 15 did not have a material impact on the amount or timing of recognition of reported revenue.

The Group has adopted the following practical expedients in adopting AASB 15:

- for services revenue, an entity is not required to adjust the transaction price for the effects of a significant financing component if the entity expects, at contract inception, that the period between customer payment and the transfer of goods or services will be one year or less. Service transaction from inception to transfer of services to the customer for the Group are generally one year or less;
- the Group does not capitalise any sales commissions payable as the amortisation profile would be less than one year if the costs were to be capitalised.

Mayne Pharma implemented AASB 9 Financial Instruments effective 1 July 2018.

The new standard changes the classification and measurement of financial instruments. The new standard requires impairments to be based on a forward-looking model determined using the expected credit loss model, changes the approach to hedging financial exposures and related documentation and amends disclosure requirements. The impairment of financial assets including trade receivables is now assessed using an expected credit loss model; previously, the incurred loss model was used.

All financial assets that are within the scope of AASB 9 are required to be measured at amortised cost or fair value, with movements through other comprehensive income or the income statement based on the Group's business model for managing the financial assets and the contractual cash flow characteristics of the financial assets.

The accounting policy change has been applied retrospectively and did not have any material effect on the financial position, hedge accounting, the performance of the Group or the classification in the financial statements.

G. Reclassification of comparatives

Where required, items in the 2018 comparative period have been reclassified to reflect the current presentation and enable better comparison between periods. Reclassifications mainly relate to allocations between expense categories.

NOTE 2 – REPORTING SEGMENTS

A reporting segment is a component of the Group:

- that engages in business activities from which it may earn revenues and incur expenses (including revenues and expenses relating to transactions with other components of the Group);
- whose operating results are regularly reviewed by the Group's chief operating decision maker to make decisions about resources to be allocated to the reporting segment and assess its performance; and
- for which discrete financial information is available.

The Group is organised into reporting segments which are based on products and services delivered and geographical markets.

Reporting segments that meet the quantitative criteria as prescribed by AASB 8 are reported separately. However, a reporting segment that does not meet the quantitative criteria is still reported separately where information about the segment would be useful to users of the financial statements.

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

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

The Consolidated Entity operates in four reporting segments being, Generic Products (GPD), Specialty Brands (SBD), Metrics Contract Services (MCS), and Mayne Pharma International (MPI).

GPD

GPD's revenue and gross profit are derived principally from the manufacture and distribution of generic pharmaceutical products in the US.

MCS

MCS' revenue and gross profit are derived from providing contract pharmaceutical development and manufacturing services to third-party customers principally in the US.

SBD

SBD's revenue and gross profit are derived principally from the marketing and distribution of specialty branded pharmaceutical products in the US.

MPI

MPI's revenue and gross profit are derived principally from the Australian manufacture and sale of branded and generic pharmaceutical products globally (ex-US) and provision of contract manufacturing services to third party customers within Australia.

The Consolidated Entity reports the following information on the operations of its identified reporting segments:

	GENERIC PRODUCTS \$'000	METRICS CONTRACT SERVICES \$'000	SPECIALTY BRANDS \$'000	MAYNE PHARMA INTERNATIONAL \$'000	TOTAL \$'000
Year ended 30 June 2019					
Sale of goods	320,774	-	91,555	27,721	440,050
Services revenue	-	72,202	-	10,544	82,746
Licence fee revenue	-	-	-	1,162	1,162
Royalty revenue	-	-	-	1,250	1,250
Revenue	320,774	72,202	91,555	40,677	525,208
Cost of sales	(156,240)	(36,669)	(11,729)	(30,635)	(235,273)
Gross profit	164,534	35,533	79,826	10,042	289,935
Other income					2,731
Amortisation of intangible assets					(78,862)
Asset impairments					(351,716)
Other expenses (refer Statement Profit or Loss and Other Comprehensive Income)					(215,805)
(Loss) / Profit before income tax					(353,717)
Income tax expense					69,966
Net (Loss) / Profit for the period					(283,751)

The combined revenue from the largest customer from each reporting segment was \$162.4m for the year ended 30 June 2019.

Approximately 50% of the Group's 2019 revenue (2018: 53%) was derived from the three largest customers which is not unusual for operations in the US pharmaceutical market where most of the branded and generic sales are made to a small number of key wholesale and retail organisations. These three customers trade with both the GPD and SBD segments.

	GENERIC PRODUCTS \$'000	METRICS CONTRACT SERVICES \$'000	SPECIALTY BRANDS \$'000	MPI \$'000	TOTAL \$'000
Year ended 30 June 2018					
Sale of goods	385,704	-	44,683	25,614	456,001
Services revenue	-	63,082	-	10,058	73,140
Royalty revenue	-	-	-	1,172	1,172
Revenue	385,704	63,082	44,683	36,844	530,313
Cost of sales	(208,308)	(29,411)	(7,151)	(28,894)	(273,764)
Gross profit	177,396	33,671	37,532	7,950	256,549
Other income					2,691
Amortisation of intangible assets					(70,200)
Asset impairments					(184,374)
Other expenses (refer Statement Profit or Loss and Other Comprehensive Income)					(171,453)
(Loss) / Profit before income tax					(166,787)
Income tax expense					32,530
Net (Loss) / Profit for the period					(134,257)

Geographical information

<i>Revenue from external customers</i>	2019 \$'000	2018 \$'000
Australia	28,344	28,013
United States	484,548	493,470
Korea	3,446	3,175
Other	8,870	5,655
Total external revenue	525,208	530,313

<i>Revenue from customer contracts</i>	2019 \$'000	2018 \$'000
Recognised at a point in time	442,462	457,173
Recognised over time	82,746	73,140
Total revenue from customer contracts	525,208	530,313

<i>Non-current assets</i>	2019 \$'000	2018 \$'000
Australia	124,110	132,322
United States	909,553	1,152,255
Total non-current assets	1,033,663	1,284,577

Non-current assets for this purpose consist of property, plant and equipment and intangible assets.

Product information

<i>Revenue by product group/service</i>	2019 \$'000	2018 \$'000
Third party contract services and manufacturing	82,746	73,140
Generic and branded products	440,050	456,001
Other revenue	2,412	1,172
Total external revenue	525,208	530,313

Revenue recognition and measurement

From 1 July 2018, with the implementation of the AASB 15 Revenue from contracts with customers, the Group accounting policy for revenue recognition is as follows:

Sale of goods

The Group receives revenue for the supply of goods to customers against orders received. The contracts that Mayne Pharma enters into relate to sales orders containing single performance obligations for the delivery of pharmaceutical products. The average duration of the sales order is less than 12 months.

Product revenue is recognised when control of the goods is passed to the customer. The point at which control passes is determined by each customer arrangement, but generally occurs on delivery to the customer.

Product revenue represents net sales value including variable consideration. The variable consideration is estimated at contract inception under the 'expected value method'. Variable consideration arises on the sale of goods as a result of discounts and allowances as well as accruals for estimated returns, rebates, chargebacks and government health care deductions (described further below). The methodology and assumptions used to estimate these variable considerations are monitored and adjusted regularly in light of contractual and legal obligations, historical trends, past experience and market conditions. Revenue is not recognised in full until it is highly probable that a significant reversal in the amount of cumulative revenue recognised will not occur. Amounts expected to be settled via credits are shown net of trade receivables while amounts expected to be settled by payments are shown as accruals.

Variable consideration

Consistent with pharmaceutical industry practices, Mayne Pharma's gross sales are subject to various deductions which are primarily composed of rebates and discounts to retail customers, government agencies, wholesalers, health insurance companies and managed healthcare organisations. These deductions represent estimates of the related obligations, requiring use of judgement when estimating the effect of these sales deductions on gross sales for a reporting period. These adjustments are deducted from gross sales to arrive at net sales.

The following summarises the nature of some of these deductions and how the deductions are estimated. After recording these, net sales represent the Group's best estimate of the cash that it expects to ultimately collect. The US market has the most complex arrangements related to revenue deductions.

US specific healthcare plans and program rebates

The United States Medicaid Drug Rebate Program is a partnership between Centers for Medicare and Medicaid Services (CMS), State Medicaid Agencies, and participating drug manufacturers that helps to offset the Federal and State costs of most outpatient drugs dispensed to Medicaid patients. Calculating the rebates to be paid related to this program involves interpreting relevant regulations, which are subject to challenge or change in interpretative guidance by government authorities. Accruals for estimating Medicaid rebates are calculated using a combination of historical experience, product and population growth, product pricing and the mix of contracts and specific terms in the individual State agreements. The United States Federal Medicare Program aids Medicare eligible recipients by funding healthcare benefits to individuals aged 65 or older and those with certain disabilities, providing prescription drug benefits under Part D section of the program. This Part D benefit is provided and administered through private prescription drug plans. Accruals for estimating Medicare Part D rebates are calculated based on the terms of individual plan agreements, product sales and population growth, product pricing and the mix of contracts. We offer rebates to key managed healthcare and private plans to sustain and increase sales of our products. These programs provide a rebate after the plans have demonstrated they have met all terms and conditions set forth in their contract with the Group. These rebates are estimated based on the terms of individual agreements, historical experience, product pricing, and projected product growth rates. These accruals are adjusted based on established processes and experiences from filing data with individual states and plans. There is often a time lag of several months between the Group recording the revenue deductions and the final accounting for them.

The Group offers rebates to key managed healthcare and private plans to sustain and increase sales of products. These programs provide a rebate after the plans have demonstrated they have met all terms and conditions set forth in the contracts with the Group. These rebates are estimated based on the terms of individual agreements, historical experience and product pricing.

These provisions are adjusted based on established processes and experiences from filing data with individual states and plans. There is often a time lag of several months between the Group recording the revenue deductions and the final accounting for them.

Non-healthcare plans and program charge-backs, rebates, returns and other deductions

The Group offers rebates to purchasing organisations and other direct and indirect customers to sustain and increase market share for products. Since rebates are contractually agreed upon, the related provisions are estimated based on the terms of the individual agreements, historical experience, and projected product growth rates.

Charge-backs occur where the Group has arrangements with indirect customers to sell products at prices that are lower than the price charged to wholesalers. A charge-back represents the difference between the invoice price to the wholesaler and the indirect customer's contract price. The Group accounts for vendor charge-backs by reducing revenue for the estimate of charge-backs attributable to a sales transaction. Provisions for estimated charge-backs are calculated using a combination of factors such as historical experience, product growth rates, payments, product pricing, level of inventory in the distribution channel and the terms of individual agreements.

When a product is sold providing a customer the right to return, the Group records a provision for estimated sales returns based on sales return policy and historical return rates. Other factors considered include actual product recalls, expected marketplace changes, the remaining shelf life of the product, and the expected entry of generic products. No value for returned inventory is recognised as all returned inventory is destroyed.

The Group offers cash discounts to customers to encourage prompt payment. Cash discounts are estimated and accrued at the time of invoicing and are deducted from revenue. Other sales discounts, such as co-pay discount cards, are offered in some markets. The estimated amounts of these discounts are recorded at the time of sale and are estimated utilising historical experience and the specific terms for each program. If a discount for

a probable future transaction is offered as part of a sales transaction, then an appropriate portion of revenue is deferred to cover this estimated obligation.

The accruals are adjusted periodically to reflect actual experience. To evaluate the adequacy of accrual balances, the Group uses internal and external estimates of the inventory in transit, the level of inventory in the distribution and retail channels, actual claims data received and the time lag for processing rebate claims. External data sources include reports from wholesalers.

Following a decrease in the price of a product, the Group generally grants customers a "shelf-stock adjustment" for their existing inventory for the relevant product. Accruals for shelf stock adjustment are determined at the time of the price decline, or at the point of sale if the impact of a price decline on the products sold can be reasonably estimated based on the customer's inventory levels of the relevant product.

Profit-sharing revenue represents the Group's share of the net profit from the sale of generic pharmaceutical products based on agreements with distribution partners. Amounts are typically based on calculated profits net of cost of goods sold, distribution expenses, chargebacks, returns and related accruals as reported by the distribution partners.

Product return allowances are calculated for products that may be returned due to expiration dates or recalls. The Group and its distribution partners do not expect any significant product returns that are not adequately covered by the reserve amounts calculated and recorded by the distribution partners.

Services revenue

Services revenue relates to commercial manufacturing, development and analytical services for third parties. These contracts give rise to fixed and variable consideration from upfront payments and development milestones.

Commercial manufacturing services contain performance obligations that are satisfied over time and are generally measured using the output method based on units produced. Under this method, revenue is recognised at the time that the product manufacture has been completed and it has passed through quality assurance reviews. This method reflects a reasonable approximation of the progress of satisfying the performance obligation based on the production time from commencing manufacturing to completion. Once a product passes through quality assurance, it has been verified that the product was manufactured in accordance with specified processes and controls, therefore, it is unlikely that the product would contain significant non-conformities.

Pharmaceutical development and analytical services performance obligations are satisfied over time and measured using the output method based on the type of work being performed. Development and analytical services are based on specific milestones and customer contracts include an enforceable right to payment for performance completed to date. Examples of output measures include completion of formulation report, analytical and stability testing or clinical batch production reports.

The Company has applied the practical expedient method as permitted by the accounting standard as performance obligations have an expected duration of one year or less.

Royalties revenue

Royalties arising from manufacturing rights are recognised when earned in accordance with the relevant agreement.

License fee revenue

Some of the Group's revenues are generated from licensing agreements under which third parties have been granted rights to products and technologies. Consideration received, or expected to be received, that relates to the sale or out licensing of technologies or technological expertise is recognised in profit or loss as of the effective date of the agreement if all rights relating to the technologies and all obligations resulting from them have been relinquished under the contract terms. However, if rights to the technologies continue to exist, or obligations resulting from them have yet to be fulfilled, the consideration received is deferred accordingly. Any consideration deferred is recorded as contract liabilities and recognised in profit or loss over the estimated performance period stipulated in the agreement.

Interest revenue

Revenue is recognised as interest accrues using the effective interest method. This is a method of calculating the amortised cost of a financial asset and allocating the interest revenue over the relevant period using the effective interest rate, which is the rate that exactly discounts estimated future cash receipts through the expected life of the financial asset to the net carrying amount of the financial asset.

NOTE 3 – FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES

The Group's principal financial instruments comprise cash, short-term deposits, receivables, payables, bank loans and interest rate swaps.

The Group manages its exposure to key financial risks, including credit risk, interest rate risk, currency risk and liquidity risk in accordance with the Group's financial risk management framework. The objective of the framework is to support the delivery of the Group's financial targets whilst protecting future financial security.

The main risks arising from the Group's financial instruments are interest rate risk, foreign currency risk, credit risk and liquidity risk. The Group uses different methods to measure and manage different types of risks to which it is exposed. These include monitoring levels of exposure to interest rate and foreign exchange risk and assessments of market forecasts for interest rate and foreign exchange rates. Liquidity risk is monitored through the development of future rolling cash flow forecasts.

Primary responsibility for identification and control of financial risks rests with the Board. The Board reviews and agrees policies for managing each of the risks identified below.

Risk exposures and responses

Interest rate risk

The Group's main interest rate risk arises from long term borrowings. Borrowings issued at variable rates expose the Group to cash flow interest rate risk. During the year the Group's borrowings at variable rates were denoted in USD and AUD. At reporting date, approximately 59% of the Group's borrowings were swapped to fixed interest.

As at the end of the reporting period, the Group had the following variable rate borrowings outstanding:

	2019 \$'000	2018 \$'000
Variable Interest-bearing loans and borrowings	374,495	378,020
Less Face value of interest rate swaps	(198,137)	(202,511)
Net variable interest rate exposure	176,358	175,509

The Group has partially hedged the USD and AUD interest rate exposures by entering into interest rate swap contracts. At 30 June 2019 the interest swaps had a face value of US\$97m (2018: US\$150m) and A\$60m (2018: A\$nil).

Interest rate swaps with a face value of US\$85.175m mature in June 2021 with the remaining USD interest rate swaps contracts (US\$11.825m) maturing in June 2020. AUD interest rate swaps mature in June 2022 (A\$60m).

The cash flow hedges are considered highly effective.

The variable interest rate risk on borrowings is partially off-set by the variable interest rate risk of cash at bank.

	2019 \$'000	2018 \$'000
Cash at bank and on hand	89,004	87,312

The following sensitivity analysis is based on the interest rate risk exposures in existence at reporting date. At reporting date, if interest rates had moved, as illustrated in the table below, with all other variables held constant, net profit and equity would have been affected as follows:

	NET PROFIT/(LOSS)		EQUITY	
	2019 \$'000	HIGHER/(LOWER) 2018 \$'000	2019 \$'000	HIGHER/(LOWER) 2018 \$'000
US interest rates +0.5% (50 basis points)	(53)	(491)	-	-
AUD interest rates +0.5% (50 basis points)	(215)	45	-	-

The movements are due to higher/lower interest expense on borrowings less/plus lower/higher interest revenue from cash balances. Possible movements in interest rates were determined based on the current observable market environment.

Foreign currency risk

The Group has significant transactional currency exposures arising from sales and purchases in currencies other than the functional currency of the parent entity. Approximately 93% of the Group's revenues and 84% of the Group's costs are denominated in currencies other than the functional currency of the parent entity.

It is the Group's general policy to enter into simple Forward Exchange Contracts over a set percentage of the forecast net receipts of US dollars. The percentages used vary depending on the length of the forecast period (0-3 months and 4-6 months). The Group does not have any Forward Exchange Contracts at reporting date (2018: nil).

From time to time, the Company enters into FX contracts to manage the FX exposure of the Company relating to loans advanced to US subsidiaries denoted in USD. No FX contracts were outstanding at reporting date relating to intra-group loans.

The Group also holds assets and liabilities in US dollars (USD), British pounds (GBP), Japanese yen (JPY), Canadian dollars (CAD) and Euro (EUR). The existence of both assets and liabilities denominated in USD provides a limited natural hedge against adverse currency movements for USD denoted exposures.

At balance date the Group's only significant foreign exchange exposure was to US dollar monetary assets and US dollar monetary liabilities as shown in the table below:

	A\$'000 30 JUNE 2019	A\$'000 30 JUNE 2018
Cash at bank	15,149	49,416
Other financial assets	563	15,063
Trade receivables	539	606
Intra Group loans receivable	216,504	352,623
Prepayments	4,272	-
Trade and other payables	(2,377)	(1,731)
Other financial liabilities	(437)	-
Interest-bearing borrowings	(227,855)	(374,110)
Net exposure which may impact Net Profit/(Loss)	6,358	41,867
Intra Group loans receivable	242,096	472,526
Net exposure which may impact equity	242,096	472,526

The following table demonstrates the sensitivity to a reasonably possible change in the USD exchange rate, with all other variables held constant. The impact on the Group's profit before tax is due to changes in the fair value of monetary assets and liabilities. The Group's exposure to foreign currency changes for all other currencies is not material.

	NET PROFIT/(LOSS)		EQUITY	
	2019 \$'000	HIGHER/(LOWER) 2018 \$'000	2019 \$'000	HIGHER/(LOWER) 2018 \$'000
AUD/USD +5%	(303)	(773)	(11,528)	(22,501)
AUD/USD -5%	334	847	12,738	24,870

The movements are due to foreign currency gains or losses as a result of changes in the balances of cash, borrowings, and the net of receivables and payables.

Credit risk

Credit risk arises from the financial assets of the Group, which comprise cash and cash equivalents, interest rate swaps and trade and other receivables. The Group's exposure to credit risk arises from potential default of the counter party, with a maximum exposure equal to the carrying amount of the financial assets.

The Group does not hold any credit derivatives to offset its credit exposure. The Group trades only with recognised, creditworthy third parties, and as such collateral is not requested. The Group holds limited credit insurance in the US which would only apply for small customers in the US.

Management of credit risk

It is the Group's policy that all customers who wish to trade on credit terms are subject to credit verification procedures including an assessment of their independent credit rating, financial position, experience and industry reputation.

Approximately 50% of the Group's 2019 revenue was derived from the three largest customers which is not unusual for operations in the US pharmaceutical market where most of both branded and generic sales are made to a small number of key wholesale and retail organisations. The Group had three customers who comprised approximately 76% of the total trade receivables balance at reporting date. These customers were operating within agreed trading terms at the end of the FY19 period.

The Group believes that there is minimal credit risk on the above key customer concentration as there has never been any default on their obligations and they are major US pharmaceutical wholesale/retail organisations with investment grade credit ratings. The Group does not hold collateral as security.

Impairment of financial assets is considered using a forward-looking expected credit loss ('ECL') approach. Receivables are monitored on an ongoing basis and the incidence of bad debt write off has been extremely low. The calculation reflects the probability-weighted outcome, the time value of money and reasonable and supportable information that is available at the reporting date about past events, current conditions and forecasts of future economic conditions.

Financial assets included on the Consolidated Statement of Financial Position that potentially subject the Group to concentration of credit risk consist principally of cash and cash equivalents, interest rate swaps and trade receivables. The Group minimises this concentration of risk by placing its cash and cash equivalents with financial institutions that maintain superior independent credit ratings to limit the degree of credit exposure. The maximum exposures to credit risk as at 30 June 2019 in relation to each class of recognised financial assets is the carrying amount of those assets, as indicated in the Consolidated Statement of Financial Position.

Credit quality of financial assets:

	2019 \$'000	2018 \$'000
Cash and cash equivalents ¹	89,004	87,312
Trade and other receivables ²	256,580	252,715
Interest rate swaps	-	6,747
	345,584	346,774

- Notes:
1. Minimum of S&P AA rated counterparty with which deposits are held.
 2. At period end 2019 trade receivables were \$251,460,000, with 92% of trade receivables within trading terms.

Liquidity risk

Liquidity risk arises from the financial liabilities of the Group and the Group's subsequent ability to meet its obligations to repay its financial liabilities as and when they fall due.

The Group's objective is to maintain a balance between continuity of funding and flexibility using bank loans and cash and short-term deposits sufficient to meet the Group's current cash requirements. Risk is managed by spreading loan maturities.

The Board manages liquidity risk by monitoring, monthly, the total cash inflows and outflows expected over the budget and forecast period.

The following table discloses the remaining contractual maturities for the Group's liquid financial assets and liabilities based on undiscounted cash flows. The timing of cash flows for liabilities is based on the contractual terms of the underlying contract.

	LESS THAN 6 MONTHS \$'000	6 TO 12 MONTHS \$'000	1 TO 5 YEARS \$'000	GREATER THAN 5 YEARS \$'000	TOTAL \$'000
30 June 2019					
Liquid financial assets					
Cash and cash equivalents	89,004	-	-	-	89,004
Trade and other receivables	256,580	-	-	-	256,580
	345,584	-	-	-	345,584
Financial liabilities					
Trade and other payables	(129,942)	-	-	-	(129,942)
Interest-bearing loans and borrowings	(50,881)	-	(323,614)	-	(374,495)
Other financial liabilities	(2,915)	(10,570)	(60,473)	(21,695)	(95,652)
	(183,738)	(10,570)	(384,087)	(21,695)	(600,089)
Net inflow/(outflow)	161,846	(10,570)	(384,087)	(21,695)	(254,505)

	LESS THAN 6 MONTHS \$'000	6 TO 12 MONTHS \$'000	1 TO 5 YEARS \$'000	GREATER THAN 5 YEARS \$'000	TOTAL \$'000
30 June 2018					
Liquid financial assets					
Cash and cash equivalents	87,312	-	-	-	87,312
Trade and other receivables	252,715	-	-	-	252,715
	340,027	-	-	-	340,027
Financial liabilities					
Trade and other payables	(152,561)	-	-	-	(152,561)
Interest-bearing loans and borrowings	(29)	(29)	(378,042)	-	(378,100)
Other financial liabilities	(798)	(11,678)	(6,335)	(298)	(19,109)
	(153,388)	(11,707)	(384,377)	(298)	(549,770)
Net inflow/(outflow)	186,639	(11,707)	(384,377)	(298)	(209,743)

The Group has undrawn loan facilities of US\$172.8m, undrawn working capital facilities of A\$10m and US\$10m and undrawn receivables financing of US\$24.3m available at reporting date. Refer Note 16.

NOTE 4 – OTHER INCOME

	2019 \$'000	2018 \$'000
Rental from excess office space	249	192
Net foreign exchange gains	689	-
Gain on remeasurement of HPPI warrants (refer Note 5)	-	1,622
Other	777	765
	1,715	2,579

Lease revenue

Rental income arising from the operating lease on a building at the Salisbury manufacturing site is accounted for on a straight-line basis over the lease term and included in other income due to its operating nature.

NOTE 5 – FAIR VALUE MEASUREMENT

Fair value measurement

The Group measures financial instruments, such as derivatives, at fair value at each reporting date.

Fair value is the price that would be received to sell an asset, or paid to transfer a liability, in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either:

- in the principal market for the asset or liability; or
- in the absence of a principal market, in the most advantageous market for the asset or liability.

The principal or the most advantageous market must be accessible by the Group. The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, if market participants act in their economic best interest.

A fair value measurement of a non-financial asset considers a market participant's ability to generate economic benefits by using the asset in its highest and best use or by selling it to another market participant that would use the asset in its highest and best use.

The Group uses valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximising the use of relevant observable inputs and minimising the use of unobservable inputs.

All assets and liabilities for which fair value is measured or disclosed in the financial statements are categorised within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

- 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

For assets and liabilities that are recognised in the financial statements on a recurring basis, the Group determines whether transfers have occurred between levels in the hierarchy by re-assessing categorisation (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each reporting period.

The Group determines the policies and procedures for fair value measurement.

External valuers are involved for valuation of significant assets and significant liabilities, such as contingent consideration. Involvement of external valuers is decided upon annually. Selection criteria include market knowledge, reputation, independence and whether professional standards are maintained.

At each reporting date, the Group analyses the movements in the values of assets and liabilities which are required to be re-measured or re-assessed as per the Group's accounting policies. For this analysis, the Group verifies the significant inputs applied in the latest valuation by agreeing the information in the valuation computation to contracts and other relevant documents.

The Group also compares each of the changes in the fair value of each asset and liability with relevant external sources to determine whether the change is reasonable.

The Group's external valuers provide the valuation results. The results and underlying assumptions are discussed with the Audit & Risk Committee and/or the Group's independent auditors.

For fair value disclosures, the Group has determined classes of assets and liabilities based on the nature, characteristics and risks of the asset or liability and the level of the fair value hierarchy as explained above.

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

	CARRYING AMOUNT		FAIR VALUE	
	2019 \$'000	2018 \$'000	2019 \$'000	2018 \$'000
Assets				
Warrants (options) - HPPI	563	8,316	563	8,316
Mark to market valuation - interest rate swap contracts	-	6,747	-	6,747
Liabilities				
Earn-out and deferred consideration liabilities	73,438	17,827	73,438	17,827
Mark to market valuation - interest rate swap contracts	437	-	437	-

Cash and short-term deposits and trade and other receivables approximate their carrying amounts largely due to the short-term maturities of these instruments.

Warrants represent options to purchase shares in HPPI. A summary of the number of warrants and exercise prices are included in Note 11. The warrants have been recognised at fair value using the Black-Scholes method. Key inputs in determining the fair value of the warrants were the share price and the share price volatility. The share price volatility used in the valuation was 55% (2018: 65%) and was based on the Nasdaq Bio-tech index over 5 years. A change in the share price volatility to 65% would increase the warrants value by approximately 35% in US dollar terms.

The earn-out liabilities payable utilises present value calculation techniques that are not based on observable market data. The key inputs are forecast sales and gross margin.

Deferred consideration recognised includes amounts which have contingent conditions such as FDA approvals and on market conditions (eg. timing of commercial launches, no entry of a new competitor into the relevant market). 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.

A variation in the discount rate of 1% would impact earn-out and deferred consideration liabilities by approximately \$1.8m. A variation in sales performance by 5% would impact earn-out liabilities by approximately \$1.7m. Unexpected changes to the timing of product commercial launches and/or entry of a new competitor into the relevant market would further change the deferred consideration liability amounts depending on the timing of the event.

Fair values of the Group's interest-bearing borrowings and loans approximate book values as loans are at market rates. The Group's own non-performance risk at reporting date was assessed as insignificant.

Assets and liabilities measured at fair value

As at 30 June 2019, the Group held the following financial instruments carried at fair value in the Statement of Financial Position:

	LEVEL 2		LEVEL 3	
	2019 \$'000	2018 \$'000	2019 \$'000	2018 \$'000
Financial Assets				
Warrants (options)	-	-	563	8,316
Mark to market valuation - interest rate swap contracts	-	6,747	-	-
Financial Liabilities				
Earn-out and deferred consideration liabilities	-	-	73,438	17,827
Mark to market valuation - interest rate swap contracts	437	-	-	-

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:

	2019 \$'000	2018 \$'000	2019 \$'000	2018 \$'000
	WARRANTS	WARRANTS	EARN-OUT & DEFERRED CONSIDERATION LIABILITIES	EARN-OUT & DEFERRED CONSIDERATION LIABILITIES
Opening balance	8,316	6,208	17,827	40,953
Additions recognised for acquisitions made during current year	475	486	55,916	-
Fair value movement	(8,228)	1,622	7,295	(326)
Amounts settled	-	-	(9,290)	(23,417)
Restatement of foreign currency balances	-	-	1,690	617
Closing balance	563	8,316	73,438	17,827

NOTE 6 – EXPENSES

	2019 \$'000	2018 \$'000
Finance costs		
Interest expense – syndicated loans	13,855	12,610
Interest expense – receivables finance	842	-
Unused line fees	1,633	1,800
Amortisation of borrowing costs	1,657	1,355
Gain on modification of syndicated loan facility	(516)	-
Gain on cancellation of interest rate swap contracts reclassified	(1,840)	-
Interest expense – finance leases	75	60
Change in fair value attributable to the unwinding of the discounting of the earn-out and deferred consideration liabilities ¹	1,813	1,482
	17,519	17,307
Depreciation²	15,635	9,683
Cost of sales include the following:		
Inventory write offs	24,535	18,185
Inventory provision for obsolescence and net realisable value adjustments	(7,258)	9,499
Onerous supply contracts	-	3,097
Employee benefits expense³		
Wages and salaries	115,680	102,883
Superannuation expense	4,920	4,448
Other employee benefits expense	8,917	9,954
Share-based payments (refer Note 26) (includes cancelled shares in pcp as noted below)	9,004	14,490
Total employee benefits	138,521	131,775
Administration and other expenses include the following:		
Drug pricing investigations and related litigation costs	2,677	672
Share-based payments expense for cancelled shares	-	7,412
Share-based payments expense (excludes amounts relating to cancelled shares as above)	9,004	7,078
Fair value loss on restatement of HPPI warrants	8,228	-
Restructuring expenses	-	5,834
Foreign exchange losses	-	220
Amortisation of intangible assets	78,862	70,200
Movement in undiscounted fair value of earn-out and deferred consideration liabilities ⁴	5,482	(1,808)
All other administration and other expenses	67,694	56,479
Total administration and other expenses	171,947	146,087

- Notes:
- The non-cash unwinding of the discount relates to all earn-out and deferred consideration liabilities.
 - Depreciation expense is included in cost of sales (\$12,675,000), Research and development expenses (\$2,729,000) and Administration and other expenses (\$232,000).
 - Employee benefit expense is included in various expense categories and cost of sales.
 - The movement in the undiscounted fair value of earn-out liabilities and deferred settlement liabilities of \$5,482,000 (2018: \$1,808,000 credit) was a non-cash (credit)/charge relating to re-assessment of the underlying assumptions for various earn-out and deferred settlement liabilities.

NOTE 7 – INCOME TAX

A. The major components of income tax expense are:

	2019 \$'000	2018 \$'000
<i>Income tax benefit / (expense)</i>		
Current income tax	(1,057)	1,632
Adjustment in respect of current income tax of previous years	102	2,126
Deferred income tax	70,921	28,772
Income tax expense in the consolidated statement of profit or loss and other comprehensive income	<u>69,966</u>	<u>32,530</u>
<i>Deferred income tax benefit/(expense) included in income tax expense comprises</i>		
Increase in deferred tax assets	65,104	163
Decrease in deferred tax liabilities	5,817	28,609
	<u>70,921</u>	<u>28,772</u>

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

	2019 \$'000	2018 \$'000
The prima facie tax on operating profit differs from the income tax provided in the accounts as follows:		
Profit/(loss) before income tax	(353,717)	(166,787)
Prima facie tax benefit/(expense) at 30%	106,115	50,036
Effect of R&D concessions	2,328	1,110
Over/(under) provision in respect of prior years	102	2,126
Non-deductible expenses for tax purposes		
Share-based payments	(2,175)	(4,389)
Asset impairment - Goodwill	-	(11,400)
Amortisation intangibles	(1,625)	(1,625)
Other non-deductible expenses	(7,392)	441
Non-assessable income	2,078	11,162
Tax losses not recognised	(1,649)	(8,473)
Effect of different tax rate in US compared to Australia	(32,589)	(3,476)
US state taxes	7,987	5,687
Restatement of DTA & DTL re US tax rate changes	(3,214)	(8,669)
Income tax expense	<u>69,966</u>	<u>32,530</u>

C. Recognised deferred tax assets and liabilities

	2019 \$'000	2018 \$'000
Deferred tax assets		
Intangible assets	88,053	29,537
Provisions	9,300	5,981
Payables	23,548	15,819
Carry forward tax losses and R&D credits	13,474	11,659
Inventory	6,281	7,633
US state taxes	9,357	7,529
Other	446	2,243
	<u>150,459</u>	<u>80,401</u>
Reconciliation to the Statement of Financial Position		
Total Deferred Tax Assets	150,459	80,401
Set-off of Deferred Tax Liabilities that are expected to reverse in the same period	(19,738)	(15,237)
Net Deferred Tax Assets ¹	<u>130,721</u>	<u>65,164</u>

Note: 1. Represent Australian and US Deferred Tax Assets that cannot be offset.

	2019 \$'000	2018 \$'000
Deferred tax asset movements		
Opening balance	80,401	80,677
Credit/(charge) to profit/loss	65,104	163
Credit/(charge) to other comprehensive income	-	-
Credit direct to equity ¹	25	(1,324)
Restatement of foreign currency balances	4,929	885
Balance at 30 June 2019	<u>150,459</u>	<u>80,401</u>

Note: 1. Amounts credited to equity relate to tax effect of share-based payments.

	2019 \$'000	2018 \$'000
Deferred tax liabilities		
Property, plant and equipment	14,822	13,742
Intangible assets	22,686	32,637
Unrealised foreign exchange gains	8,274	-
Prepayments	2,907	-
US state taxes	2,390	2,870
Other	19	18
	51,098	49,267
Reconciliation to the Statement of Financial Position		
Total Deferred Tax Liabilities	51,098	49,267
Set-off of Deferred Tax Assets that are expected to reverse in the same period	(19,738)	(15,237)
Net Deferred Tax Liabilities ¹	31,360	34,030

	2019 \$'000	2018 \$'000
Deferred tax liability movements		
Opening balances	49,267	76,385
Charge/(credit) to profit/loss	(5,817)	(28,609)
Charge/(credit) to other comprehensive income	5,972	-
Restatement of foreign currency balances	1,676	1,491
Balance at 30 June 2019	51,098	49,267

Note: 1. Represent US Deferred Tax Liabilities that cannot be offset.

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

Income tax and other taxes

Current tax assets and liabilities for the current and prior periods are measured at the amount expected to be recovered from or paid to the taxation authorities based on the current period's taxable income. The tax rates and tax laws used to compute the amount are those that are enacted or substantively enacted by the reporting date.

Deferred income tax is provided on all temporary differences at the reporting date between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes.

Deferred income tax assets are recognised for all deductible temporary differences, carry-forward of unused tax credits and unused tax losses, to the extent that it is probable that taxable profit will be available against which the deductible temporary differences and the carry-forward of unused tax credits and unused tax losses can be utilised.

The carrying amount of deferred income tax assets is reviewed at each reporting date and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred income tax asset to be utilised.

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.

Deferred income tax assets and liabilities are measured at the tax rates that are expected to apply to the year when the asset is realised, or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted at the reporting date.

Income taxes relating to items recognised directly in equity are recognised in equity and not in profit or loss.

Deferred tax assets and deferred tax liabilities are offset only if a legally enforceable right exists to set off current tax assets against current tax liabilities and the deferred tax assets and liabilities relate to the same taxable entity and the same taxation authority.

The Company and its wholly-owned Australian controlled entities have implemented the tax consolidation legislation. These entities are taxed as a single entity and the deferred tax assets and liabilities of these entities are set off in the consolidated financial statements.

US federal corporate tax changes

The US legislation Tax Cuts and Jobs Act enacted in December 2017 means that Mayne Pharma's operations in the US were subject to a federal income tax rate of 21% for the whole of FY19. Income tax expense (above) for the current period relating to Mayne Pharma's US operations has therefore been determined using the federal corporate tax rate of 21% whereas the federal blended corporate rate of 28.1% applied for the prior period.

Due to the US federal corporate tax rate changes, US denoted deferred tax assets and US denoted deferred tax liabilities that were expected to reverse in FY19 or beyond were restated using the 21% rate during the prior period. As Mayne Pharma has a net US denoted deferred tax asset, this has resulted in an additional tax expense in the prior period - the Restatement of DTA & DTL re US tax rate changes tax expense as disclosed above. This restatement includes changes to the blended US state corporate income tax rate which varies depending on activity and tax rates in the US states in which Mayne Pharma operates.

Tax consolidation legislation

The Company and its wholly-owned Australian controlled entities are part of an income tax consolidated group.

The Company and its controlled entities in the income tax consolidated group continue to account for their own current and deferred tax amounts. The Group has applied the 'separate taxpayer within group' approach in determining the appropriate amount of current taxes and deferred taxes to allocate to the members of the income tax consolidated group.

In addition to its own current and deferred tax amounts, the Company also recognises the current tax liabilities (or assets) and the deferred tax assets arising from unused tax losses and unused tax credits assumed from controlled entities in the income tax consolidated group.

Each company in the Group contributes to the income tax payable by the Group in proportion to their contribution to the Group's taxable income.

Assets or liabilities arising under the tax funding agreement with the income tax consolidated entities are recognised as amounts receivable from or payable to other entities in the Group.

Any difference between the amounts assumed and amounts receivable or payable under the tax funding agreement are recognised as a contribution to (or distribution from) wholly-owned income tax consolidation entities.

Significant accounting judgements

Deferred tax assets

The Group's accounting policy for taxation requires management's judgement in assessing whether deferred tax assets are recognised in the Consolidated Statement of Financial Position. Deferred tax assets, including those arising from un-recouped tax losses, capital losses and temporary differences, are recognised only where it is considered more likely than not that they will be recovered, which is dependent on the generation of sufficient future taxable profits.

Assumptions about the generation of future taxable profits depend on management's estimates of future cash flows. These depend on estimates of future revenues, operating costs, capital expenditure and other capital management transactions. Judgements are also required about the application of income tax legislation in the jurisdictions in which the Group operates and the application of the arm's length principle to related party transactions. These judgements and assumptions are subject to risk and uncertainty, hence there is a possibility that changes in circumstances will alter expectations, which may affect the carrying amount of deferred tax assets and liabilities. Any resulting adjustment to the carrying value of a deferred tax item will be recorded in the Statement of Profit or Loss and Other Comprehensive Income.

NOTE 8 – EARNINGS PER SHARE

	2019	2018
Earnings per share for profit attributable to the ordinary equity holders of the Parent:		
Basic earnings per share	(19.04) cents	(9.16) cents
Diluted earnings per share	(19.04) cents	(9.16) cents

Basic earnings per share is calculated by dividing the profit for the year attributable to ordinary equity holders of the Parent by the weighted average number of ordinary shares outstanding during the year.

Diluted earnings per share is calculated by dividing the profit for the year attributable to ordinary equity holders of the Parent by the weighted average number of ordinary shares outstanding during the year plus the weighted average number of shares that would be issued on conversion of all the dilutive potential ordinary shares into ordinary shares.

The following reflects the income and share data used in the basic and diluted EPS calculations:

	2019 \$'000	2018 \$'000
For basic earnings per share		
Net profit attributable to equity holders of the Company	(280,866)	(133,984)
For diluted earnings per share		
Net profit attributable to equity holders of the Company	(280,866)	(133,984)
	2019 '000	2018 '000
Weighted average number of ordinary shares for basic earnings per share	1,475,091	1,462,867
<i>Effect of dilution (based on average share price during the year):</i>		
Share options and LTI shares	11,613	5,174
Weighted average number of ordinary shares adjusted for the effect of dilution	1,486,704	1,468,041

The calculation of weighted average number of ordinary shares adjusted for the effect of dilution does not include the following options and LTI shares which could potentially dilute basic earnings per share in the future, but were not dilutive in the periods presented (as the exercise price is greater than the average share price during the year):

	2019 '000	2018 '000
Number of potential ordinary shares	42,983	85,700

There have been no subsequent transactions involving ordinary shares or potential ordinary shares that would significantly change the number of ordinary shares or potential ordinary shares outstanding at the end of the reporting period.

NOTE 9 – TRADE AND OTHER RECEIVABLES

	2019 \$'000	2018 \$'000
Current		
Trade receivables (net of charge-backs)	251,460	252,013
Trade receivables – profit share	219	292
Provision for impairment	(696)	(635)
Other receivables	5,597	1,045
	256,580	252,715

At 30 June, the ageing analysis of trade receivables is as follows:

	NOT PAST DUE NOR IMPAIRED WITHIN TERMS \$'000	OVERDUE AND NOT IMPAIRED 0-30 DAYS OVERDUE \$'000	OVERDUE AND NOT IMPAIRED 30+ DAYS OVERDUE \$'000	TOTAL \$'000
Trade receivables 30 June 2019	231,436	5,925	13,622	250,983
Trade receivables 30 June 2018	245,065	1,830	4,775	251,670

Trade and other receivables

Trade receivables are initially recognised at their invoiced amounts less adjustments for estimated revenue deductions such as charge-backs and cash discounts. The Group's trade receivables are measured at amortised cost.

Due to the short-term nature of these receivables, their carrying value approximates their fair value.

Some of the Group's receivables are sold under the receivables financing program (refer note 16). The Group considers the economic substance rather than the legal form of the transactions in assessing the business model of the underlying receivables, accordingly, transactions that fail AASB 9 derecognition criteria are not considered true sales and thus, the business model of the underlying receivables continues to be holding to collect contractual cash flows and therefore are measured at amortised cost.

Receivables sold on a non-recourse basis total US\$25.7m at balance date. The book value of the receivables approximates the value the finance provided. Receivables are sold with no recourse to Mayne Pharma in relation to credit risk, although the receivables continue to be recognised on the Group's balance sheet as accounting derecognition criteria has not been met as Mayne Pharma retains certain risks in relation to the variability of charge-backs, rebates, returns and loyalty programs. Also refer note 16.

Trade receivables are non-interest bearing and are generally on 30-90-day terms. As at reporting date, \$696,000 (2018: \$635,000) of receivables were considered impaired. Trade receivables – profit share is due on 90-day terms. None of these receivables are considered impaired at reporting date.

From 1 July 2018, with the adoption of AASB 9 Financial Instruments, provisions for expected credit losses are established using an expected loss model (ECL). The provisions are based on a forward-looking ECL, which includes possible default events on the trade receivables over the entire holding period of the trade receivables. These provisions represent the difference between the trade receivable's carrying amount in the consolidated balance sheet and the estimated collectible amount. For trade receivables, the Group applies a simplified approach in calculating ECLs. Therefore, the Group does not track changes in credit risk, but instead recognises a loss allowance based on lifetime ECLs at each reporting date. The Group has established a provision matrix that is based on its historical credit loss experience, adjusted for forward-looking factors specific to the debtors and the economic environment.

Significant accounting judgements

Customer charge-backs and discounts

Consistent with pharmaceutical industry practices, Mayne Pharma's gross sales are subject to various deductions including charge-backs and discounts. These deductions represent estimates of the related obligations, requiring use of judgement when estimating the effect of these sales deductions on gross sales for a reporting period. These adjustments are deducted from gross sales to arrive at net sales. (Refer note 2 for Revenue recognition policy).

Amounts expected to be settled via credits are shown net of trade receivables while amounts expected to be settled by payments are shown as accruals.

Other receivables include amounts recoverable under supply contracts and outstanding for goods and services tax (GST). These amounts are non-interest bearing and have repayment terms applicable under the relevant government authority. Other balances within trade and other receivables do not contain impaired assets and are not past due. It is expected that these other balances will be received when due.

NOTE 10 – INVENTORIES

	2019 \$'000	2018 \$'000
Raw materials and stores at cost	34,191	33,625
Work in progress at cost	18,996	7,546
Finished goods at lower of cost and net realisable value	47,161	40,985
	100,348	82,156

Recognition and measurement

Inventories

Inventories are valued at the lower of cost and net realisable value. Costs incurred in bringing each product to its present location and conditions are accounted for as follows:

- *Raw materials* - purchase cost on a first-in, first-out basis.
- *Finished goods and work-in-progress* - cost of direct materials and labour and a proportion of manufacturing overheads based on normal operating capacity.

The Group has recognised provisions at reporting date for obsolescence and net realisable value adjustments of \$16,197,000 (2018: \$21,793,000).

Significant accounting estimates and judgements

Net realisable value is the estimated selling price in the ordinary course of business, less estimated costs of completion and the estimated costs necessary to make the sale.

The Group assesses net realisable value and obsolescence provisions by reviewing estimated future sales, quantities on hand and the shelf life of the relevant inventory. Estimating future sales values, quantities and the timing of future sales requires management judgement. The Group may incur costs that differ from its original estimate.

NOTE 11 – OTHER FINANCIAL ASSETS

	2019 \$'000	2018 \$'000
Current		
Restricted cash	399	365
Mark to market value of interest rate swaps contracts	-	6,747
Warrants	563	8,316
	962	15,428

Restricted cash represents cash held as security for letters of credit.

The warrants represent options to acquire shares in HPPI as follows:

	EXERCISE PRICE (US CENTS)	EXPIRY DATE	BALANCE AT BEGINNING OF YEAR	ACQUIRED DURING THE YEAR	EXERCISED DURING THE YEAR	BALANCE AT END OF YEAR	2019 \$'000	2018 \$'000
			Number	Number	Number	Number		
Unlisted options	12.00	27/5/21	23,504,236	-	-	23,504,236	482	7,171
Unlisted options	23.00	9/1/20	2,608,696	-	-	2,608,696	9	497
Unlisted options	27.50	9/1/23	2,608,696	-	-	2,608,696	33	648
Unlisted options	23.00	5/7/20	-	1,739,131	-	1,739,131	11	-
Unlisted options	27.50	5/7/23	-	1,739,131	-	1,739,131	28	-
			28,721,628	3,478,262	-	32,199,890	563	8,316

The warrants have been recognised at fair value using the Black-Scholes method. A fair value decrement of \$8.2m (2018: increment \$1.6m) was recognised during the period in relation to the warrants.

In July 2018, Mayne Pharma invested an additional US\$1.6m in HPPI and received 2,318,841 Series B Preference shares, 1,739,131 "A" warrants (exercisable at \$0.23 each) and 1,739,131 "B" warrants (exercisable at \$0.275 each). The B preference shares are convertible into ordinary shares on a one preference share to three ordinary shares basis.

During the prior comparable period, Mayne Pharma invested an additional US\$2.4m in HPPI and received 3,478,261 Series B Preference shares, 2,608,696 "A" warrants (exercisable at \$0.23 each) and 2,608,696 "B" warrants (exercisable at \$0.275 each). The B preference shares are convertible into ordinary shares on a one preference share to three ordinary shares basis.

Financial Instruments

Initial recognition and subsequent measurement

A financial instrument is any contract that gives rise to a financial asset of one entity and a financial liability or equity instrument of another entity.

Financial assets are classified, at initial recognition, as financial assets at fair value through profit or loss, loans and receivables, held-to-maturity investments, available-for-sale financial assets, or as derivatives designated as hedging instruments in an effective hedge, as appropriate.

All financial assets are recognised initially at fair value plus, in the case of financial assets not recorded at fair value through profit or loss, transaction costs that are attributable to the acquisition of the financial asset.

Financial assets at fair value through profit or loss

Financial assets at fair value through profit or loss are designated upon initial recognition. Financial assets are classified as held for trading if they are acquired for selling or repurchasing in the near term. Derivatives are also classified as held for trading unless they are designated as effective hedging instruments. Financial assets with cash flows that are not solely payments of principal and interest are classified and measured at fair value through profit or loss, irrespective of the business model.

The Group holds warrants which are derivatives and are not hedging instruments and hence are held at fair value through profit or loss. Financial assets at fair value through profit or loss are carried in the statement of financial position at fair value with net changes in fair value included in the statement of profit or loss.

Forward exchange contracts

The Group uses derivative financial instruments (forward currency contracts) to hedge its risks associated with foreign currency fluctuations. These derivatives do not qualify for hedge accounting and mark to market valuation adjustments are recognised in profit or loss in income or expenses.

NOTE 12 – OTHER ASSETS

	2019 \$'000	2018 \$'000
Current		
Prepayments	24,530	20,950
	24,530	20,950

NOTE 13 – PROPERTY, PLANT AND EQUIPMENT

	LAND \$'000	BUILDINGS \$'000	PLANT AND EQUIPMENT \$'000	CAPITAL UNDER CONSTRUCTION \$'000	TOTAL \$'000
Year ended 30 June 2019					
Balance at beginning of year net of accumulated depreciation	9,306	104,978	100,060	15,707	230,051
Additions	-	1,498	5,119	5,920	12,537
Disposals	-	-	(620)	-	(620)
Transfers	-	-	8,177	(8,177)	-
Depreciation charge for year	-	(3,218)	(12,417)	-	(15,635)
Foreign currency restatement	261	4,790	4,283	367	9,701
Balance at end of year net of accumulated depreciation	9,567	108,048	104,602	13,817	236,034
At 30 June 2019					
At cost	9,567	118,921	155,989	13,817	298,294
Accumulated depreciation	-	(10,873)	(51,387)	-	(62,260)
Net carrying amount	9,567	108,048	104,602	13,817	236,034
Year ended 30 June 2018					
Balance at beginning of year net of accumulated depreciation	9,132	27,687	33,545	118,908	189,272
Additions	-	583	33,162	10,064	43,809
Transfers	-	74,825	37,763	(112,588)	-
Depreciation charge for year	-	(1,875)	(7,808)	-	(9,683)
Foreign currency restatement	174	3,758	3,398	(677)	6,653
Balance at end of year net of accumulated depreciation	9,306	104,978	100,060	15,707	230,051
At 30 June 2018					
At cost	9,306	112,296	134,333	15,707	271,642
Accumulated depreciation	-	(7,318)	(34,273)	-	(41,591)
Net carrying amount	9,306	104,978	100,060	15,707	230,051

Property, plant and equipment

Plant and equipment is stated at historical cost less accumulated depreciation and any accumulated impairment losses. Land and buildings are measured at cost less accumulated depreciation on buildings and less any impairment losses.

Property, plant and equipment is assessed for impairment whenever there is an indication that the balance sheet carrying value amount may not be recoverable using cash flow projections for the useful life.

Depreciation is calculated on a straight-line basis over the estimated useful life of the assets as follows:

Land	Not depreciated
Buildings	Over 40 years
Plant and equipment	Between 1.5 and 20 years

The assets' residual values, useful lives and amortisation methods are reviewed, and adjusted if appropriate, at each financial year-end. Gains and losses on disposals are determined by comparing proceeds with the carrying amount. These are included in the Consolidated Statement of Profit or Loss and Other Comprehensive Income.

Government grants obtained for construction activities, including any related equipment, are deducted from the gross acquisition costs to arrive at the balance sheet carrying value of the related assets.

Significant accounting estimates and assumptions

Estimation of useful lives of assets

The estimation of the useful lives of assets has been based on historical experience as well as manufacturers' warranties and lease terms. In addition, the condition of the assets is assessed at least once per year and considered against the remaining useful life. Adjustments to useful lives are made when considered necessary.

NOTE 14 – INTANGIBLE ASSETS AND GOODWILL

	GOODWILL \$'000	CUSTOMER CONTRACTS, CUSTOMER RELATIONSHIPS, PRODUCT RIGHTS AND INTELLECTUAL PROPERTY \$'000	DEVELOPMENT EXPENDITURE \$'000	MARKETING & DISTRIBUTION RIGHTS \$'000	TRADE NAMES \$'000	TOTAL \$'000
Year ended 30 June 2019						
Balance at beginning of year net of accumulated amortisation	20,616	838,286	102,225	45,429	47,970	1,054,526
Additions	-	104,086	21,759	74	-	125,919
Disposals	-	-	(93)	-	-	(93)
Amortisation	-	(67,612)	(5,114)	(1,834)	(4,302)	(78,862)
Specific impairments	-	(1,484)	(37,859)	-	-	(39,343)
CGU Impairments	-	(267,135)	(31,174)	(14,063)	-	(312,372)
Foreign currency restatement	1,109	41,627	3,629	1,302	190	47,857
Balance at end of year net of accumulated amortisation	21,725	647,768	53,373	30,908	43,858	797,632
As at 30 June 2019						
Cost	63,685	1,299,354	167,851	64,386	69,158	1,664,434
Accumulated amortisation	-	(231,908)	(14,305)	(9,370)	(25,243)	(280,826)
Accumulated impairments	(41,960)	(419,678)	(100,173)	(24,108)	(57)	(585,976)
Net carrying amount	21,725	647,768	53,373	30,908	43,858	797,632
The split between indefinite and definite life assets is as follows:						
Indefinite life assets	21,725	30,426	27,446	15,285	-	94,882
Definite life assets	-	617,342	25,549	16,001	43,858	702,750
Net carrying amount	21,725	647,768	52,995	31,286	43,858	797,632
Year ended 30 June 2018						
Balance at beginning of year net of accumulated amortisation	58,217	978,206	91,611	55,286	52,121	1,235,441
Additions	-	6,617	33,046	755	-	40,418
Amortisation	-	(59,857)	(3,397)	(2,664)	(4,282)	(70,200)
Impairments	(38,003)	(115,465)	(22,110)	(8,795)	-	(184,374)
Foreign currency restatement	402	28,785	3,075	847	131	33,240
Balance at end of year net of accumulated amortisation	20,616	838,286	102,225	45,429	47,970	1,054,526
As at 30 June 2018						
Cost	60,395	1,131,681	139,854	60,146	68,878	1,460,954
Accumulated amortisation	-	(155,473)	(8,826)	(5,443)	(20,854)	(190,596)
Accumulated impairments	(39,779)	(137,922)	(28,803)	(9,274)	(54)	(215,832)
Net carrying amount	20,616	838,286	102,225	45,429	47,970	1,054,526

Goodwill and intangibles

Goodwill arises in a business combination and is the excess of the consideration transferred to acquire a business over the underlying fair value of the net identified assets acquired. It is allocated to groups of cash-generating units (CGUs) which are usually represented by reported segments. Goodwill is tested for impairment annually at the CGU level and any impairment charges are recorded in the Consolidated Statement of Profit or Loss and Other Comprehensive Income.

Where goodwill forms part of a cash-generating unit and part of the operation within that unit is disposed of, the goodwill associated with the operation disposed of is included in the carrying amount of the operation when determining the gain or loss on disposal of the operation. Goodwill disposed of in this circumstance is measured on the relative values of the operation disposed of and the portion of the cash-generating unit retained.

The aggregate carrying amounts of goodwill are allocated to the Group's cash-generating units as follows:

	2019 \$'000	2018 \$'000
MCS	21,334	20,225
MPI	391	391
Closing goodwill balance at 30 June	21,725	20,616

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, distribution rights and trade marks) have been assessed as having finite useful lives and, as such, are amortised over their useful lives on a straight-line basis. 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. The amortisation expense on intangible assets with definite lives is recognised in profit or loss in the expense category consistent with the function of the intangible asset.

Certain marketing and distribution rights, development expenditure and other intellectual property are considered to have an indefinite life and hence are not amortised. These assets, considered on an individual asset basis, have been determined as indefinite life based on the expected life of the relevant product. The assessment of indefinite versus definite life is reviewed annually.

Significant accounting judgements

Research and development expenditure

Research costs are expensed as incurred. Development expenditures on an individual project, and acquired research and development intangible assets, which are still under development and have not yet obtained approval, are recognised as an intangible asset when the Group can demonstrate:

- the technical feasibility of completing the intangible asset so that the asset will be available for use or sale;
- its intention to complete and its ability to use or sell the asset;
- how the asset will generate future economic benefits;
- the availability of resources to complete the asset; and
- the ability to measure reliably the expenditure during development.

Following initial recognition of the development expenditure as an asset, the asset is carried at cost less any accumulated amortisation and accumulated impairment losses. Amortisation of the asset begins when development is complete, and the asset is available for use. It is amortised over the period of expected future benefit. During the period of development, the asset is tested for impairment annually.

Significant accounting estimates and assumptions

Impairment of goodwill and intangible assets

Intangible asset impairments recognised during the period totalled \$351.7m (2018: \$184.4m) following a detailed review of the Company's intangible assets (which considered the current and projected US market dynamics for the portfolio and the industry) and consisted of the following:

- Specific Development Expenditure (pipeline products) \$37.9m
- Specific acquired foam assets for certain international IP and distribution rights \$1.5m
- GPD - Other CGU assets \$312.4m

The GPD – Other impairment was allocated to all intangible assets in the CGU on a pro-rata basis as follows:

- Marketing & distribution rights \$14.2m
- Customer contracts, customer relationships, product rights and intellectual property \$267.0m
- Development expenditure \$31.2m

An asset is considered impaired when its balance sheet carrying amount exceeds its estimated recoverable amount, 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 value-in-use 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 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 (product 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.

Goodwill and intangible impairment testing methodology

For impairment testing, Intangible assets (other than Goodwill) are allocated to individual CGUs (which are the Therapeutic Groups or 'TG') which are then combined into the overall reporting segment CGUs of GPD, SBD, MCS and MPI. Goodwill testing is performed at the segment level. Assets not included in these CGUs in the prior comparative period are those related to HPPI's intellectual property.

Each segment or CGU to which the Goodwill or Intangible asset is so allocated 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 following CGU and TG structure has been determined for impairment testing:

- GPD segment with two Therapeutic Groups being 'Women's Health' (GPD WH) and 'Other' (GPD Other);
- SBD segment with one Therapeutic Group being 'Dermatology';
- MCS segment; and
- MPI segment with two Therapeutic Groups being 'Dermatology' (MPI Dermatology) and 'Other' (MPI Other).

The testing methodology for the recoverable value of each asset is as follows:

- allocate the asset value to the relevant CGU including an allocation of corporate assets and costs;
- estimate cash flows generated over the life of the CGU;
- 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 R&D in process, which were tested with specific consideration of:

- the outcome of R&D activities (product 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.

These assets, and related cashflows, have been included in the relevant CGU for impairment testing purposes and are also reviewed individually on at least an annual basis. This change in building up the value-in-use cash flows of the CGUs, which constitutes a change in accounting estimate, has been performed to better align the impairment testing of the Group's intangible assets to the way in which its operations and therapeutic groups of product portfolios are managed, and to achieve consistency with normal impairment testing and valuation practices of peer companies in the US and Europe.

As a result of individual testing, R&D in process projects were impaired totalling \$37.9m (all of which occurred in 2HFY19) (2018: \$22.2m).

HPPI's intellectual property represents a similar asset to R&D in process. This asset is tested individually and at least on an annual basis.

The allocation of intangible assets to segments is shown in the table below.

2019	MPI – Dermatology \$000	MPI – Other \$000	GPD - Other \$000	GPD – Women's Health \$000	SBD \$000	MCS \$000	TOTAL \$000
Indefinite life	26,199	861	43,658	2,830	-	21,334	94,882
Definite life	71,489	13,205	302,189	193,787	116,644	5,436	702,750
Total Intangibles	97,688	14,066	345,847	196,617	116,644	26,770	797,632

Key assumptions in impairment testing methodology include:

- CGU cash flow forecasts (including allocation of corporate overhead) are based on the FY20 Annual Budget and specific cash flows are further forecasted out to FY24;
- a terminal growth rate is applied; and
- individual CGU discount rates have been used.

Discount rates reflect management's estimate of the time value of money and the risks specific to the CGU and have been determined using the WACC. There has been no change from those used as at 30 June 2018.

The post-tax discount rates used are shown below:

- MCS: 10.2% (FY18: 10.2%)
- SBD: 10.2% (FY18: 10.2%)
- GPD: 9.6%¹ (FY18: 9.6%)
- MPI: 9.6%² (FY18: 9.6%)

Notes: 1. The Women's Health and Other TGs in GPD also use the same WACC.
2. The Dermatology and Other TGs in MPI also use the same WACC.

A comparison of the MCS, GPD, SBD and MPI CGU segments and their related TGs assumed forecast net sales growth rates for the current year impairment testing is shown in the table below. These average growth rates are assumptions determined to satisfy applicable accounting standards but should not be used for guidance.

	FY19 ASSUMED AVERAGE FORECAST GROWTH RATES 1 st FIVE YEARS	FY19 ASSUMED TERMINAL VALUE GROWTH RATE	FY18 ASSUMED AVERAGE FORECAST GROWTH RATES 1 st FIVE YEARS	FY18 ASSUMED TERMINAL VALUE GROWTH RATE
MCS CGU forecast net sales growth	18%	2%	12%	2%
GPD CGU forecast net sales growth	-3%	-1%	-1%	-1%
<i>GPD WH TG forecast net sales growth</i>	6%	-1%	4%	-1%
<i>GPD Other TG forecast net sales growth</i>	-6%	-1%	-1%	-1%
SBD CGU forecast net sales growth	9%	-3%	20%	-3%
MPI CGU forecast net sales growth	8%	0%	17%	0%
<i>MPI Dermatology TG forecast net sales growth</i>	15%	0%	35% ¹	0%
<i>MPI Other TG forecast net sales growth</i>	2%	0%	6%	0%

Notes: 1. Growth rate for MPI Dermatology (and MPI) impacted by the effect of DORYX returns in FY18.

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

A\$m	Carrying Value ¹	Recoverable Value	Difference
MCS CGU	173.4	298.6	125.3
GPD CGU	770.1	887.2	117.1
<i>GPD WH TG</i>	239.4	356.4	117.1
<i>GPD Other TG</i>	530.8	530.8	0.0
SBD CGU	144.4	187.4	43.0
MPI CGU	185.7	504.9	319.2
<i>MPI Dermatology TG</i>	150.4	441.4	291.0
<i>MPI Other TG</i>	35.3	63.5	28.2

Notes: 1. Includes intangible assets, goodwill, working capital and property, plant and equipment.

Sensitivity to changes in assumptions

The table below shows the sensitivity of the changes in key variables on recoverable values.

A\$m	+/-1% Change in Net Sales Growth ¹	+/-1% Change in Terminal Growth Rate	+/-1% Change in WACC
MCS CGU	+16/-15	+34/-27	-35/+45
GPD CGU	+36/-35	+52/-43	-67/+81
<i>GPD WH TG</i>	+13/-12	+24/-20	-29/+35
<i>GPD Other TG</i>	+24/-23	+28/-23	-38/+45
SBD CGU	+11/-11	+11/-10	-15/+17
MPI CGU	+20/-19	+23/-18	-25/+31
<i>MPI Dermatology TG</i>	+17/-17	+17/-14	-19/+24
<i>MPI Other TG</i>	+3/-3	+5/-4	-6/+7

Note: 1. Change refers to the movement in net sales growth rates for launched products from FY20 to FY24.

Estimation of useful lives of assets

The estimation of the useful lives of intangible assets has been based on the assets' contractual lives for the expected period of the future cash flows. The valuation assumptions used are assessed at least annually and considered against the useful life and adjustments to useful lives are made when considered necessary.

During the year ended 30 June 2018 KAPANOL[®] was reassessed from an indefinite life asset to a 10-year definite life asset. The impact of this change for the prior period was to increase amortisation expense by \$1.4m.

NOTE 15 – TRADE AND OTHER PAYABLES

	2019 \$'000	2018 \$'000
Current		
Trade payables	50,443	63,888
Accrued rebates, returns and loyalty programs	53,282	66,096
Other payables	26,216	22,577
	129,942	152,561

Information regarding liquidity risk exposure is set out in Note 3.

Trade and other payables

Trade payables and other payables are carried at amortised cost. They represent liabilities for goods and services provided to the Group prior to the end of the financial year that are unpaid and arise when the Group becomes obliged to make future payments in respect of the purchase of these goods and services. The amounts are unsecured and are usually paid within 30 days of recognition.

Included in other payables is a contract liability (\$1.9m) for which the service is expected to be completed during FY20.

Significant accounting judgements

Customer rebates, returns and loyalty programs

Consistent with pharmaceutical industry practices, Mayne Pharma's gross sales are subject to various deductions which are primarily composed of rebates and discounts to retail customers, government agencies, wholesalers, health insurance companies and managed healthcare organisations. These deductions represent estimates of the related obligations, requiring use of judgement when estimating the effect of these sales deductions on gross sales for a reporting period. These adjustments are deducted from gross sales to arrive at net sales. (Refer note 2 for Revenue recognition policy).

Amounts expected to be settled via credits are shown net of trade receivables while amounts expected to be settled by payments are shown as accruals.

NOTE 16 – INTEREST-BEARING LOANS AND BORROWINGS

	2019 \$'000	2018 \$'000
Current		
Syndicated loan (working capital facility)	14,241	-
Receivables financing	36,620	-
Lease liabilities	20	58
	<u>50,881</u>	<u>58</u>
	2019 \$'000	2018 \$'000
Non-current		
Syndicated loan	318,501	374,110
Lease liabilities	-	22
	<u>318,501</u>	<u>374,132</u>

Syndicated loan and working capital facilities

The loan facility is supported by a syndicate of seven banks and was extended in December 2018. The loan facility limit is US\$400m comprising a 3-year US\$150m term loan and a 5-year US\$250m revolving facility. The facility can be drawn in either USD or AUD.

Working capital facilities of A\$10m and US\$20m are also available. The working capital facilities were for a two-year period and were due to mature 28 July 2019. These facilities were extended to 30 November 2021 subsequent to balance date.

The total amount drawn, across all facilities, at 30 June 2019 was US\$160m and A\$110m (2018: US\$280m, A\$nil).

The facilities are unsecured and incur interest based on either LIBOR (for USD) with no floor, or BBSY (for AUD) plus a margin based on a net debt leverage ratio. The facilities are subject to certain covenants and have an unused line fee payable based on the undrawn amounts.

The Group complied with the covenants at reporting date. The Directors believe there is no risk of default at reporting date.

At 30 June 2019, the average variable interest rate was 3.223% (30 June 2018: 4.205%). The Group has entered into interest rate swap contracts to hedge the interest rate risk exposure with 61% of the outstanding US dollar loan amount and 55% of the AUD loan amount hedged at 30 June 2019 (US loans 30 June 2018: 54%, AUD loans nil). The interest rate risk is managed using interest rate swaps in which the Group agrees to exchange, at specific intervals, the difference between fixed and variable rate interest amounts calculated by reference to an agreed-upon notional principal amount.

During the period, Mayne Pharma converted USD borrowing to AUD borrowings and cancelled several US LIBOR interest rate swaps as part of the USD borrowings were converted to AUD borrowings. The cancellation of the interest rate swaps resulted in a gain of \$1.8m which was transferred to the profit or loss account from the cash flow hedge reserve. New interest rate swap contracts were entered into during the period to hedge AUD borrowings.

As Mayne Pharma renegotiated the syndicated facility during the period with a lower margin, a gain of \$0.5m on the modification of the loan was recognised in the profit or loss account.

Receivables financing facility

The receivables facility was established in December 2018. The facility is a committed facility, has a 364-day term, has a limit of US\$50m and was drawn to US\$25.7m at reporting date. Receivables are sold with no recourse to Mayne Pharma in relation to credit risk and generally roll each 90 days as each debtor pays amounts outstanding. The receivables continue to be recognised on the Group's balance sheet as accounting derecognition criteria has not been met as Mayne Pharma retains certain risks in relation to the variability of charge-backs, rebates, returns and loyalty programs.

Loan maturities are summarised as follows:

	2019 \$'000	2018 \$'000
Current	50,881	-
Non-current	323,614	378,020
	<u>374,495</u>	<u>378,020</u>
Due by 30 June 2020	50,881	202,510
Due by 30 June 2021	-	-
Due by 30 June 2022	213,614	175,510
Due by 30 June 2023	-	-
Due by 30 June 2024	110,000	-
	<u>374,495</u>	<u>378,020</u>

There were no defaults or breaches on any loans during the year ended 30 June 2019.

<i>Changes in liabilities arising from financing activities</i>	PERIOD ENDED	OPENING BALANCE \$'000	CASH FLOWS \$'000	FOREIGN EXCHANGE MOVEMENTS \$'000	CLOSING BALANCE \$'000
Interest bearing loans and borrowings	30 June 2019	374,190	(22,605)	17,797	369,382
Interest bearing loans and borrowings	30 June 2018	340,246	18,717	15,227	374,190

Recognition and measurement

Interest-bearing loans and borrowings

Borrowings are classified as current liabilities unless the Group has an unconditional right to defer settlement of the liability for at least 12 months after the reporting date. After initial recognition, interest-bearing loans and borrowings are subsequently measured at amortised cost using the effective interest method. Fees paid on the establishment of loan facilities that are yield related are included as part of the carrying amount of the loans and borrowings.

Leases

The determination of whether an arrangement is or contains a lease is based on the substance of the arrangement and requires an assessment of whether the fulfilment of the arrangement is dependent on the use of a specific asset or asset and the arrangement conveys a right to use the asset.

Finance leases, which transfer to the Group substantially all the risks and benefits incidental to ownership of the lease item are capitalised at the inception of the lease at the fair value of the leased asset or, if lower, at the present value of the minimum lease payments. Lease payments are apportioned between the finance charges and reduction of the lease liability to achieve a constant rate of interest on the remaining balance of the liability. Finance charges are recognised as an expense in profit or loss.

NOTE 17 – OTHER FINANCIAL LIABILITIES

	2019 \$'000	2018 \$'000
Current		
Mark to market value of interest rate swaps contracts	437	-
Earn-out liabilities – various products/distribution rights	5,118	916
Deferred consideration – various products/distribution rights	7,655	11,321
Completion of clinical studies obligation relating to acquired asset	712	240
	<u>13,922</u>	<u>12,477</u>
Non-Current		
Completion of clinical studies obligation relating to acquired asset	540	-
Earn-out liabilities – various products/distribution rights	26,779	1,442
Deferred consideration – various products/distribution rights	32,634	3,908
	<u>59,953</u>	<u>5,350</u>

The consolidated entity has recognised various earn-out liabilities relating to various asset purchases. Most of the earn-outs are based on a percentage of net sales and are typically payable on a quarterly to annual basis for a period of between two and ten years.

Deferred consideration recognised includes amounts which have contingent conditions such as FDA approvals and on market conditions (eg. no entry of a new competitor into the relevant market). 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.

Earn-out and deferred consideration liabilities

Recognition and derecognition

Earn-out liabilities of the Group are initially recognised on the consolidated statement of financial position as part of business combinations and intangible asset acquisitions at fair value. Financial liabilities are derecognised when they are extinguished.

Subsequent measurement

After initial recognition, earn-out liabilities are recognised at fair value through profit or loss and are remeasured each reporting period. Movements in the liability from these changes are recognised in profit or loss.

Significant accounting estimates and assumptions

Earn-out and deferred consideration liabilities

The earn-out liabilities have been determined based on contracted royalty rates payable on expected future cash flows. 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 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. Any changes in fair value for changes in the net present value of estimated future payments are recognised in the 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 \$1,813,000 (2018: \$1,482,000) for the period.

At 30 June 2019 the deferred consideration amounts consist mainly of amounts which are subject to FDA approvals, no new competitors entering the market or similar milestone requirements.

NOTE 18 – PROVISIONS

	2019 \$'000	2018 \$'000
Current		
Employee benefits	15,161	13,157
Restructuring provision	1,424	2,472
	16,585	15,629
Non-Current		
Employee benefits	766	763
Restoration	350	350
	1,116	1,113

Provisions and employee benefits

Provisions are recognised when the Group has a present obligation (legal or constructive) due to a past event, it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation and a reliable estimate can be made of the amount of the obligation.

Provisions are measured at the present value of management's best estimate of the expenditure required to settle the present obligation at the reporting date. If the effect of the time value of money is material, provisions are discounted using a current pre-tax rate that reflects the time value of money and the risks specific to the liability.

Employee leave benefits

Liabilities for wages and salaries, including non-monetary benefits and annual leave expected to be settled within 12 months of the reporting date are recognised in respect of employees' services up to the reporting date. They are measured at the amounts expected to be paid when the liabilities are settled. Liabilities for non-accumulating sick leave are recognised when the leave is taken and are measured at the rates paid or payable.

Long service leave

The liability for long service leave is recognised in the provision for employee benefits and measured as the present value of expected future payments to be made in respect of services provided by employees up to the reporting date using the projected unit credit method. Consideration is given to expected future wage and salary levels, experience of employee departures, and periods of service. Expected future payments are discounted using market yields at the reporting date on high quality corporate bonds with terms to maturity and currencies that match, as closely as possible, the estimated future cash outflows.

Restoration provision

The restoration provision represents the present value of anticipated costs for the future restoration of the Salisbury site. The outflows are expected to occur over 20 years.

Significant accounting estimates and assumptions

Restoration provision

The provision represents the present value of anticipated costs for future restoration of the Salisbury site. The calculation of this provision requires assumptions such as application of environmental legislation, timing of restoration and cost estimates. These uncertainties may result in future actual expenditure differing from the amounts currently provided.

NOTE 19 – CONTRIBUTED EQUITY

Movements in contributed equity

	2019 Number	2018 Number	2019 \$'000	2018 \$'000
Balance at beginning of year	1,564,722,158	1,510,929,673	1,131,761	1,130,404
Issued during the year:				
Tax effect of employee share options	-	-	24	(1,324)
Shares issued as part settlement for an asset acquisition	6,155,621	-	5,392	-
Other shares issued	65,000	35,000	96	52
Options exercised	4,604,000	5,115,000	2,766	2,629
Equity raising costs	-	-	(31)	-
LTI shares issued (restricted) ¹	12,340,754	73,593,458	-	-
LTI shares forfeited	(4,951,012)	(8,851,961)	-	-
LTI shares cancelled	-	(16,099,012)	-	-
Balance at end of year	1,582,936,521	1,564,722,158	1,140,008	1,131,761

Notes: 1. The shares were granted under the ESLS and SLS (and are subject to risk of forfeiture).

Contributed equity

Ordinary shares are classified as equity. Incremental costs directly attributable to the issue of new shares or options are shown in equity as a deduction from the proceeds.

A. Terms and conditions of contributed equity

Holders of ordinary shares are entitled to receive dividends as declared from time to time and are entitled to one vote per share at shareholders' meetings.

In the event of winding up of the Company, ordinary shareholders rank after all other shareholders and creditors and are fully entitled to any proceeds of liquidation.

B. Capital management

The primary objective of the Group in relation to capital management is to ensure that it maintains a strong credit rating and healthy capital ratios to support its business objectives and to maximise shareholder value.

The Group manages its capital structure and adjusts it considering changes in economic conditions and the Company's strategy. To maintain or adjust the capital structure, the Company may return capital to shareholders or issue new shares. During the year ended 30 June 2019 the Company issued new shares and amended available debt facilities. No changes were made in the objectives, policies or processes during the years ended 30 June 2019 and 30 June 2018.

The Group includes within net debt, interest-bearing loans and borrowings, less cash and cash equivalents. The Group's current policy is to maintain a net debt position within policy limits set by the directors and that can be serviced by the Group's cash flows.

	2019 \$'000	2018 \$'000
Interest-bearing borrowings	369,382	374,190
Less cash and cash equivalents	(89,004)	(87,312)
Net debt	280,378	286,878

The Group is subject to a minimum level of shareholder funds under the terms of the syndicated loan facility. The Group complies at reporting date.

NOTE 20 – RESERVES

	2019 \$'000	2018 \$'000
Share-based payments reserve	28,644	20,813
Cash flow hedge reserve	(437)	6,747
Other reserve	(3,143)	(3,721)
Foreign currency translation reserve	100,035	47,339
	125,099	71,178

Share-based payments reserve

The share-based payments reserve records the value of share-based payments provided to employees, including KMP, as part of their remuneration.

	2019 \$'000	2018 \$'000
Balance at beginning of year	20,813	14,890
Share-based payments expense	9,004	14,490
Transfer to contributed equity on exercise of options	(1,173)	(1,155)
Transfer to retained earnings on cancellation of employee shares	-	(7,412)
Balance at end of year	28,644	20,813

Cash flow hedge reserve

The cash flow hedge reserve records the portion of the gain or loss on a hedging instrument in a cash flow hedge that is determined to be an effective hedge relationship.

	2019 \$'000	2018 \$'000
Balance at beginning of year	6,747	1,415
Mark to market unrealised gain / (loss) on interest rate swap contracts	(7,184)	5,332
Balance at end of year	(437)	6,747

Other equity reserve

The Other equity reserve records movements in the Group's equity in partly-owned subsidiaries after recognising changes to non-controlling interests.

	2019 \$'000	2018 \$'000
Balance at beginning of year	(3,721)	(4,020)
Change to equity investment in HPPI	578	299
Balance at end of year	(3,143)	(3,721)

Foreign currency translation reserve

Exchange differences arising on translation of the foreign controlled entities are recognised in Other Comprehensive Income as described in Note 1C and accumulated in a separate reserve within equity. Exchange differences arising on monetary items that form part of the reporting entity's net investment in a foreign operation are recognised in profit or loss in the separate financial statements of the reporting entity. In the Group's financial statements that include the foreign operation and the reporting entity, such exchange differences are recognised initially in other comprehensive income. The cumulative amount is reclassified to profit and loss when the net investment is disposed of except for cumulative exchange differences relating to non-controlling interests.

	2019 \$'000	2018 \$'000
Balance at beginning of year	47,339	11,052
Foreign exchange translation differences (net of tax)	52,696	36,287
Balance at end of year	100,035	47,339

NOTE 21 – RETAINED EARNINGS

	2019 \$'000	2018 \$'000
Retained earnings at the beginning of the period	23,525	150,097
Transfer from share-based payments reserve re cancelled employee shares	-	7,412
Net (loss) / profit attributable to members	(280,866)	(133,984)
Retained earnings at the end of the period	(257,341)	23,525

NOTE 22 – NOTES TO THE CONSOLIDATED STATEMENT OF CASH FLOWS

A. Cash and cash equivalents

Cash and cash equivalents in the Statement of Financial Position and for the purposes of the Statement of Cash Flows comprise cash at bank and in hand (excluding restricted cash) and short-term deposits with an original maturity of three months or less that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value.

Cash and cash equivalents at the end of the year as shown in the Statement of Financial Position and the Statement of Cash Flows comprise the following:

	2019 \$'000	2018 \$'000
Cash at bank and on hand	89,004	87,312

Cash at bank attracts floating interest at current market rates.

B. Reconciliation of net profit after income tax to net cash used in operating activities

	2019 \$'000	2018 \$'000
Net (loss) / profit after income tax	(283,751)	(134,257)
<i>Adjustments for:</i>		
Depreciation	15,636	9,683
Amortisation of intangibles and borrowing costs	80,519	71,448
Share-based payments	9,004	14,490
Movement in earn-out liability	7,295	(325)
Asset impairments	351,716	184,374
Gain on modification of syndicated loan facility	(516)	-
Book value of intangibles disposed	92	-
Loss / (gain) on restatement of HPPI warrants	8,228	(1,622)
Net unrealised foreign exchange differences	3,675	1,556
Non-cash provisions	(7,258)	11,863
Changes in tax balances		
(Increase) in deferred tax assets	(65,104)	(163)
Increase in current and deferred tax liabilities	16,163	(40,334)
Operating cash flows before working capital movements	135,699	116,713
Changes in working capital		
Decrease / (Increase) in receivables	9,430	(17,775)
Decrease / (Increase) in inventories	(6,430)	17,122
(Increase) / decrease in other assets	(2,409)	(8,680)
(Decrease) / increase in creditors	(30,030)	10,133
Increase / (decrease) in provisions	347	3,985
Working capital (investment) / release	(29,092)	4,785
Net cash from operating activities	106,606	121,498

NOTE 23 – RELATED PARTY DISCLOSURES

A. Subsidiaries

The consolidated financial statements include the financial statements of the Company and the subsidiaries listed in the following table:

	COUNTRY OF INCORPORATION	% EQUITY INTEREST		INVESTMENT \$'000	
		2019	2018	2019	2018
Mayne Pharma International Pty Ltd	Australia	100	100	39,205	39,205
Mayne Products Pty Ltd1	Australia	100	100	-	-
Mayne Pharma UK Limited1	United Kingdom	100	100	-	-
Mayne Pharma Inc	United States	100	100	712,799	82,708
Mayne Pharma Ventures Pty Ltd	Australia	100	100	-	-
Mayne Pharma Ventures LLC1	United States	100	100	-	-
Swan Pharmaceuticals LLC1	United States	100	100	-	-
HedgePath Pharmaceuticals Inc	United States	53.5	53.5	25,258	23,396
Mayne Pharma SIP Pty Ltd	Australia	100	100	-	511,483
Mayne Pharma LLC	United States	100	100	-	-
Mayne Pharma (Switzerland) GmbH	Switzerland	100	100	-	-
				777,262	656,792

Note: 1. Dormant subsidiaries.

Financial information of a subsidiary which has a material non-controlling interest is as follows:

Portion of equity interest held by non-controlling interest:

	COUNTRY OF INCORPORATION	% EQUITY INTEREST	
		2019	2018
HedgePath Pharmaceuticals Inc	United States	46.5	46.5

Summarised statement of profit or loss for period ended 30 June 2019

	HPPI 2019 \$'000	HPPI 2018 \$'000
Revenue	-	-
Cost of sales	-	-
Interest income	22	13
Research and development expenses	(2,496)	(2,716)
Administration expenses	(2,354)	(1,574)
Depreciation and amortisation	(921)	(850)
Share-based payments expenses	(669)	(404)
Loss before tax	(6,417)	(5,531)
Income tax benefit	213	4,934
Loss after tax	(6,204)	(597)
Other Comprehensive income	501	380
Total Comprehensive income	(5,703)	(217)
Attributable to non-controlling interests	(2,384)	107

Summarised statement of financial position as at 30 June 2019

	HPPI 2019 \$'000	HPPI 2018 \$'000
Cash at bank	2,884	1,074
Other current assets	151	525
Intangible assets	31,712	30,953
Trade and other payables	(4,565)	(624)
Deferred tax liabilities	(7,098)	(6,935)
Total equity	23,084	24,993
Attributable to equity holders of Mayne Pharma		12,301
Attributable to non-controlling interests	6,309	8,693

B. Ultimate parent

Mayne Pharma Group Limited is the ultimate parent entity.

C. KMP

Details relating to KMP, including remuneration paid, are included in Note 24.

D. Transactions with related parties

The Company had no other transactions with KMP or other related parties during the financial years ended 30 June 2019 or 30 June 2018.

Amounts owing to Directors, Director-related parties and other related parties at 30 June 2019 and 30 June 2018 were nil.

NOTE 24 – KMP DISCLOSURES

i. Directors and other KMP

The Directors of Mayne Pharma Group Limited during the financial year were:

- Mr Roger Corbett, AO - Chairman
- Mr Scott Richards - Managing Director and Chief Executive Officer
- Hon Ron Best - Independent Non-Executive Director
- Mr Patrick Blake - Independent Non-Executive Director
- Mr Frank Condella - Independent Non-Executive Director
- Ms Nancy Dolan - Independent Non-Executive Director
- Mr William (Phil) Hodges - Independent Non-Executive Director (resigned 29 November 2018)
- Mr Bruce Mathieson - Independent Non-Executive Director
- Prof Bruce Robinson, AM - Independent Non-Executive Director
- Mr Ian Scholes - Independent Non-Executive Director

Other KMP consisted of:

- Mr Nick Freeman - Group CFO and Company Secretary
- Mr Peter Paltoglou - Chief Development Officer and Head of M&A
- Dr Ilana Stancovski - Chief Scientific Officer and Head of European Market Development
- Ms Kate Rintoul - Executive Vice President and General Counsel
- Mr Stefan Cross – President International Operations
- Mr John Ross – President Mayne Pharma USA
- Ms Lisa Pendlebury - Vice President Investor Relations and Communications
- Mr Brant Schofield – Executive Vice President Speciality Brands (appointed 8 October 2018)

ii. Compensation of KMP

	2019 \$'000	2018 \$'000
Short-term employee benefits	7,508	5,860
Post-employment benefits	254	266
Long-term benefits	68	51
Share-based payments excluding cancelled shares	4,170	3,174
Total excluding cancelled shares	12,000	9,351
Share-based payments expense relating to cancelled employee shares	-	1,843
	12,000	11,194

NOTE 25 – AUDITOR'S REMUNERATION

	2019 \$	2018 \$
Amounts received or due and receivable by EY Australia for		
Audit and review of financial statements	1,073,000	1,036,600
Non-audit services		
Tax compliance services	176,000	105,465
Other Assurance	223,500	280,029
	399,500	385,494
	1,472,500	1,422,094
	2019 \$	2018 \$
Non-audit services amounts received or due and receivable from member firms related to EY Australia		
Tax compliance and advisory services	464,464	495,400
Acquisition and other services	-	-

The above non-audit services from member firms are invoiced in USD to Mayne Pharma Inc. and are subject to foreign currency translation.

NOTE 26 - SHARE-BASED PAYMENT PLANS

The expense recognised for employee services received during the year is shown in the table below:

	2019 \$'000	2018 \$'000
Expense arising from equity-settled share-based payment transactions	9,004	7,078
Expense relating to cancelled employee shares	-	7,412
	9,004	14,490

Share-based payment transactions – recognition and measurement

The Group provides benefits to its employees (including KMP) in the form of share-based payments, whereby employees render services in exchange for shares or rights over shares (equity-settled transactions). If an employee leaves the Group prior to the vesting and the employee hasn't participated in the plan for at least three years or is not otherwise considered a 'good leaver', any share-based payment previously granted to the employee will normally be forfeited. Where an employee leaves the Group after the vesting but prior to the expiry of share-based payments granted, the employee normally has 12 months in which to exercise or the shares or options will lapse. If the Company's Employee Share Option Plan was cancelled, this would not affect the rights of employees in relation to previously issued share-based payments.

The cost of these equity-settled transactions with employees is measured by reference to the fair value of the equity instruments at the date at which they are granted. The fair value is determined using an appropriate option-pricing model, depending on the complexity of the exercise conditions. The cost is recognised, together with a corresponding increase in other capital reserves in equity, over the period in which the performance and/or service conditions are fulfilled in employee benefits expense.

The Group engaged an accredited independent valuer to determine the fair value of options issued at the date at which they are granted.

The cost of equity-settled transactions is recognised, together with a corresponding increase in equity, over the vesting period.

The dilutive effect, if any, of outstanding options is reflected as additional share dilution in the computation of diluted earnings per share (refer to note 8).

Significant accounting estimates and assumptions

Share-based payment transactions

The Group measures the cost of equity-settled transactions with employees by reference to the fair value of the equity instruments at the date at which they are granted. The fair value is determined using an appropriate option-pricing model depending on the complexity of the exercise conditions with both the Black Scholes option-pricing model and the Monte Carlo Simulation option-pricing model utilised during the period. The specific assumptions applied to the options issued during the year are provided in this note. The accounting estimates and assumptions relating to equity-settled share-based payments would have no impact on the carrying amounts of assets and liabilities within the next annual reporting period but may impact expenses and equity.

Employee share option plan (ESOP)

An employee share option plan is in place where Directors and employees of the Company may be issued with options over the ordinary shares of the Company. Shareholders last approved the plan at the AGM held on 9 November 2012. The options, issued for nil consideration, are issued in accordance with guidelines established by the Directors of the Company.

Each employee option converts to one ordinary share in the Company upon exercise. The options carry neither rights to dividends, nor voting rights. Options may be exercised at any time from the date of vesting to the date of their expiry. The exercise price is set by reference to the volume weighted average price at which the Company's shares trade on the Australian Securities Exchange (ASX) across an agreed period. The contractual term varies across the various issues but generally ranges from three to six years and there are no cash settlement alternatives for employees.

No options were issued during the year ended 30 June 2019 (2018: nil) under the ESOP and the plan is not expected to be utilised going forward.

	2019 NUMBER OF OPTIONS	2019 WEIGHTED AVERAGE EXERCISE VALUE \$	2018 NUMBER OF OPTIONS	2018 WEIGHTED AVERAGE EXERCISE VALUE \$
Balance at beginning of year	8,929,000	0.5260	15,954,000	0.4661
Granted during the year	-	-	-	-
Exercised during financial year	(4,604,000)	0.3669	(5,115,000)	0.2989
Forfeitures and lapses	(2,305,000)	0.7178	(1,910,000)	0.6339
Balance at end of year	2,020,000	0.6697	8,929,000	0.5260

Share Options granted to employees

	EXERCISE PRICE	EXPIRY DATE	BALANCE AT BEGINNING OF YEAR NUMBER	GRANTED DURING THE YEAR NUMBER	EXERCISED DURING THE YEAR NUMBER	OTHER MOVEMENTS DURING THE YEAR NUMBER ¹	BALANCE AT END OF YEAR NUMBER	OPTIONS EXERCISABLE AT END OF YEAR NUMBER
Year ended 30 June 2019								
Unlisted options	\$0.2184	12/01/19	2,600,000	-	(2,600,000)	-	-	-
Unlisted options	\$0.2184	26/01/19	569,000	-	(569,000)	-	-	-
Unlisted options	\$0.5923	21/10/19	320,000	-	-	(200,000)	120,000	120,000
Unlisted options	\$0.6647	11/11/19	1,000,000	-	(500,000)	(500,000)	-	-
Unlisted options	\$0.6754	30/11/19	1,000,000	-	-	(500,000)	500,000	500,000
Unlisted options	\$0.8003	28/03/19	540,000	-	(510,000)	(30,000)	-	-
Unlisted options	\$0.7701	19/06/19	600,000	-	(125,000)	(475,000)	-	-
Unlisted options	\$0.8188	30/06/19	400,000	-	-	(400,000)	-	-
Unlisted options	\$0.8109	2/07/19	200,000	-	-	-	200,000	200,000
Unlisted options	\$0.7437	1/08/19	200,000	-	-	(200,000)	-	-
Unlisted options	\$0.7682	28/08/19	600,000	-	-	-	600,000	300,000
Unlisted options	\$0.5347	1/02/20	900,000	-	(300,000)	-	600,000	300,000
			8,929,000	-	(4,604,000)	(2,305,000)	2,020,000	1,420,000

Note: 1. Options were forfeited on the termination of employment.

No options were issued to executives under the ESOP during the year ended 30 June 2019.

	EXERCISE PRICE	EXPIRY DATE	BALANCE AT BEGINNING OF YEAR NUMBER	GRANTED DURING THE YEAR NUMBER	EXERCISED DURING THE YEAR NUMBER	OTHER MOVEMENTS DURING THE YEAR NUMBER ¹	BALANCE AT END OF YEAR NUMBER	OPTIONS EXERCISABLE AT END OF YEAR NUMBER
YEAR ENDED 30 JUNE 2018								
Unlisted options	\$0.2184	12/01/19	4,295,000	-	(1,695,000)	-	2,600,000	2,600,000
Unlisted options	\$0.2184	26/01/19	2,449,000	-	(1,880,000)	-	569,000	569,000
Unlisted options	\$0.3184	1/07/19	500,000	-	(500,000)	-	-	-
Unlisted options	\$0.5923	21/10/19	320,000	-	-	-	320,000	120,000
Unlisted options	\$0.6647	11/11/19	1,000,000	-	-	-	1,000,000	500,000
Unlisted options	\$0.6754	30/11/19	1,000,000	-	-	-	1,000,000	500,000
Unlisted options	\$0.8003	28/03/19	600,000	-	-	(60,000)	540,000	510,000
Unlisted options	\$0.7701	19/06/19	600,000	-	-	-	600,000	510,000
Unlisted options	\$0.8188	30/06/19	700,000	-	-	(300,000)	400,000	200,000
Unlisted options	\$0.8109	2/07/19	400,000	-	-	(200,000)	200,000	200,000
Unlisted options	\$0.7437	1/08/19	200,000	-	-	-	200,000	-
Unlisted options	\$0.7682	28/08/19	600,000	-	-	-	600,000	300,000
Unlisted options	\$0.6447	17/12/19	600,000	-	(300,000)	(300,000)	-	-
Unlisted options	\$0.5347	1/02/20	2,690,000	-	(740,000)	(1,050,000)	900,000	600,000
			15,954,000	-	(5,115,000)	(1,910,000)	8,929,000	6,609,000

No options were issued to executives under the ESOP during the year ended 30 June 2018.

Shares granted to employees

Under the ESLS and SLS, eligible employees acquire shares in the Company funded by a limited-recourse loan from the Group. While shares are acquired under the plan for legal and taxation purposes, Australian Accounting Standards require the shares be treated as options for accounting purposes. As a result, the amounts receivable from employees in relation to these loans are not recognised in the financial statements.

The number of notional shares granted to employees under the ESLS is set out below:

Year ended 30 June 2019	GRANT DATE	EXPIRY DATE	LOAN VALUE PER SHARE	NUMBER HELD AT 1 JULY 2018	NUMBER GRANTED DURING YEAR	NUMBER EXERCISED DURING YEAR	NUMBER LAPSED, FORFEITED OR CANCELLED DURING THE YEAR ¹	NUMBER HELD AT 30 JUNE 2019
Unlisted shares	4 Dec 14	4 Dec 19	\$0.6815	3,823,529	-	-	-	3,823,529
Unlisted shares	2 Feb 15	2 Feb 20	\$0.6163	833,003	-	-	-	833,003
Unlisted shares	3 Aug 15	31 Aug 20	\$1.1000	9,699,455	-	-	(843,244)	8,856,211
Unlisted shares	5 Aug 15	31 Aug 20	\$1.1538	194,999	-	-	(194,999)	-
Unlisted shares	24 Aug 15	31 Aug 20	\$1.1297	2,231,344	-	-	-	2,231,344
Unlisted shares	11 Nov 15	31 Aug 20	\$1.0200	215,954	-	-	(215,954)	-
Unlisted shares	11 Nov 15	31 Aug 20	\$1.0460	524,070	-	-	-	524,070
Unlisted shares	4 Dec 15	31 Aug 20	\$1.2300	2,553,496	-	-	-	2,553,496
Unlisted shares	11 Aug 16	31 Jul 21	\$2.0100	235,200	-	-	(88,200)	147,000
Unlisted shares	6 Dec 16	31 Jul 21	\$1.5760	2,242,005	-	-	-	2,242,005
Unlisted shares	3 Jan 17	31 Jan 22	\$1.3720	2,556,000	-	-	-	2,556,000
Unlisted shares	9 Feb 17	31 Jan 22	\$1.2770	322,179	-	-	-	322,179
Unlisted shares	3 Jul 17	31 Jul 22	\$1.1307	19,532,476	-	-	(971,995)	18,560,481
Unlisted shares	28 Sep 17	31 Jul 22	\$0.6631	7,129,916	-	-	(30,370)	7,099,546
Unlisted shares	26 Oct 17	31 Jul 22	\$0.7071	414,359	-	-	-	414,359
Unlisted shares	7 Dec 17	31 Jul 22	\$0.6169	6,608,851	-	-	-	6,608,851
Unlisted shares	23 Mar 18	31 Mar 23	\$0.7620	35,536,836	-	-	(2,524,877)	33,011,959
Unlisted shares	3 Sep 18	1 Oct 2023	\$1.1326	-	2,825,000	-	-	2,825,000
Unlisted shares	1 Oct 2018	1 Oct 2023	\$1.2752	-	796,754	-	-	796,754
Unlisted shares	8 Oct 2018	1 Oct 2023	\$1.2909	-	2,489,627	-	-	2,489,627
Unlisted shares	6 Dec 2018	1 Oct 2023	\$0.9696	-	6,229,373	-	-	6,229,373
				94,653,672	12,340,754	-	(4,869,639)	102,124,787

Note: 1. Not all shares forfeited by employees during the period have been cancelled prior to period end. The balance of forfeited shares was transferred to an employee share trust pending new employee grants.

Year ended 30 June 2018	GRANT DATE	EXPIRY DATE	LOAN VALUE PER SHARE	NUMBER HELD AT 1 JULY 2017	NUMBER GRANTED DURING YEAR	NUMBER EXERCISED DURING YEAR	NUMBER LAPSED, FORFEITED OR CANCELLED DURING THE YEAR ¹	NUMBER HELD AT 30 JUNE 2018
Unlisted shares	8 Sep 14	8 Sep 19	\$0.7636	1,092,063	-	-	(1,092,063)	-
Unlisted shares	4 Dec 14	4 Dec 19	\$0.6815	3,823,529	-	-	-	3,823,529
Unlisted shares	2 Feb 15	2 Feb 20	\$0.6163	833,003	-	-	-	833,003
Unlisted shares	3 Aug 15	31 Aug 20	\$1.1000	10,734,191	-	-	(1,034,736)	9,699,455
Unlisted shares	5 Aug 15	31 Aug 20	\$1.1538	974,997	-	-	(779,998)	194,999
Unlisted shares	24 Aug 15	31 Aug 20	\$1.1297	2,231,344	-	-	-	2,231,344
Unlisted shares	11 Nov 15	31 Aug 20	\$1.0200	1,079,772	-	-	(863,818)	215,954
Unlisted shares	11 Nov 15	31 Aug 20	\$1.0460	524,070	-	-	-	524,070
Unlisted shares	4 Dec 15	31 Aug 20	\$1.2300	2,553,496	-	-	-	2,553,496
Unlisted shares	11 Aug 16	31 Jul 21	\$2.0100	18,022,917	-	-	(17,787,717)	235,200
Unlisted shares	26 Sep 16	31 Jul 21	\$1.9558	427,000	-	-	(427,000)	-
Unlisted shares	11 Oct 16	31 Jul 21	\$2.0000	242,000	-	-	(242,000)	-
Unlisted shares	25 Oct 16	31 Jul 21	\$1.9139	186,779	-	-	(186,779)	-
Unlisted shares	6 Dec 16	31 Jul 21	\$1.5760	2,242,005	-	-	-	2,242,005
Unlisted shares	3 Jan 17	31 Jan 22	\$1.3720	3,378,000	-	-	(822,000)	2,556,000
Unlisted shares	9 Feb 17	31 Jan 22	\$1.2770	1,548,938	-	-	(1,226,759)	322,179
Unlisted shares	3 Jul 17	31 Jul 22	\$1.1307	-	22,585,480	-	(3,053,004)	19,532,476
Unlisted shares	28 Sep 17	31 Jul 22	\$0.6631	-	7,435,432	-	(305,516)	7,129,916
Unlisted shares	26 Oct 17	31 Jul 22	\$0.7071	-	414,359	-	-	414,359
Unlisted shares	7 Dec 17	31 Jul 22	\$0.6169	-	6,608,851	-	-	6,608,851
Unlisted shares	23 Mar 18	31 Mar 23	\$0.7620	-	36,549,336	-	(1,012,500)	35,536,836
				49,894,104	73,593,458	-	(28,833,990)	94,653,672

The ESLS and SLS allows the issue of shares to participants based on a percentage of fixed remuneration funded by a limited-recourse, interest free, five-year loan for the sole purpose of acquiring the shares. Issues are typically made annually to KMP and other senior executives who have foregone an STI entitlement. These shares vest over three years subject to the achievement of hurdles based on increases in shareholder wealth created over that period. The shares are granted upfront based on the five-day volume weighted average price and remain restricted and subject to risk of forfeiture until the end of the vesting/performance period while the loan remains outstanding, with any unvested/unexercised shares lapsing 49 months after the first test date.

The number/proportion of shares that vest is based on the absolute Total Shareholder Return (TSR) over the period, with 50% vesting if a TSR of 5% (10% for pre- 1 July 2015 issues) Compound Annual Growth (CAGR) is achieved, rising to 100% vesting for achievement of a TSR CAGR of 10% (15% for pre- 1 July 2015 issues). Vesting will occur on a straight-line basis for performance between these two points.

If the CAGR performance conditions are met, 20% vest after the first test date, 30% after the second test date and the balance after the third test date. Vesting can occur over a period of 5 years (including six monthly in years 4 and 5) from the date of the grant, but the TSR vesting condition continues to compound in years 4 and 5.

The table below illustrates the required growth rates at a TSR CAGR of 5% pa which would represent 50% vesting:

	Year 1	Year 2	Year 3	Year 4	Year 5
Tranche 1 - 20% of grant	TSR +5% from base year	TSR +10% from base year	TSR +16% from base year	TSR +22% from base year	TSR +28% from base year
Tranche 2 - 30% of grant	Not available for vesting	TSR +10% from base year	TSR +16% from base year	TSR +22% from base year	TSR +28% from base year
Tranche 3 - 50% of grant	Not available for vesting	Not available for vesting	TSR +16% from base year	TSR +22% from base year	TSR +28% from base year

The table below illustrates the required growth rates at a TSR CAGR of 10% pa which would represent 100% vesting:

	Year 1	Year 2	Year 3	Year 4	Year 5
Tranche 1 - 20% of grant	TSR +10% from base year	TSR +21% from base year	TSR +33% from base year	TSR +46% from base year	TSR +61% from base year
Tranche 2 - 30% of grant	Not available for vesting	TSR +21% from base year	TSR +33% from base year	TSR +46% from base year	TSR +61% from base year
Tranche 3 - 50% of grant	Not available for vesting	Not available for vesting	TSR +33% from base year	TSR +46% from base year	TSR +61% from base year

Vesting between 50% and 100% will occur on a straight-line basis for performance between these two points.

Following the end of the applicable vesting period, if the vesting conditions are met the ESLS shares will vest and the participant will then have until the end of the five-year term, plus one month, to repay the loan.

Any dividends paid on the shares while the ESLS are restricted are applied (on a notional after-tax basis) towards repaying the loan.

The base test dates for the ESLS issues made from 1 July 2015 to 31 December 2017 were set as 1 July each year. Base test dates for grants after 31 December 2017 are either 1 March or 1 September to align with results announcements. For earlier issues the testing dates were based on the anniversary of the grant date. These grants provide a rolling benefit to senior executives over the three-year period in the absence of a short-term incentive.

In the event of a Corporate Control Event, the TSR will be measured from the base test date to the date of the Control Event date and LTI shares will vest immediately if the TSR hurdles are met. If any unvested shares do not automatically vest as a result of the Corporate Control Event, the Board may otherwise determine that some or all of those shares become vested shares.

For share options granted during the financial year (these shares are treated as options for accounting purposes) the fair value of the options granted was determined by valuation specialists, using the Monte Carlo Simulation option pricing model. The following inputs were used in the valuations:

	LTI SHARES GRANTED 3 SEPT 2018			LTI SHARES GRANTED 1 OCT 2018 ¹			LTI SHARES GRANTED 8 OCT 2018 ¹		
	TRANCHE 1	TRANCHE 2	TRANCHE 3	TRANCHE 1	TRANCHE 2	TRANCHE 3	TRANCHE 1	TRANCHE 2	TRANCHE 3
Number of shares (treated as options for accounting)	565,000	847,500	1,412,500	159,351	239,026	398,378	497,925	746,888	1,244,814
Monte Carlo Simulation model fair value	\$0.3605	\$0.4210	\$0.4570	\$0.3575	\$0.4357	\$0.4830	\$0.3280	\$0.4043	\$0.4632
Share price at grant date	\$1.175	\$1.175	\$1.175	\$1.285	\$1.285	\$1.285	\$1.260	\$1.260	\$1.260
Exercise price	\$1.1326	\$1.1326	\$1.1326	\$1.2752	\$1.2752	\$1.2752	\$1.2909	\$1.2909	\$1.2909
Expected volatility	45%	45%	45%	45%	45%	45%	45%	45%	45%
Expected option life	2.6yrs	2.9yrs	3.4yrs	2.6yrs	2.9yrs	3.3yrs	2.5yrs	2.8yrs	3.2yrs
Dividend yield	0%	0%	0%	0%	0%	0%	0%	0%	0%
Risk-free rate	1.97%	1.97%	1.97%	2.05%	2.05%	2.05%	2.12%	2.12%	2.12%

	LTI SHARES GRANTED 6 DEC 2018 ¹		
	TRANCHE 1	TRANCHE 2	TRANCHE 3
Number of shares (treated as options for accounting)	1,245,875	1,868,812	3,114,687
Monte Carlo Simulation model fair value	\$0.2365	\$0.2947	\$0.3296
Share price at grant date	\$0.955	\$0.955	\$0.955
Exercise price	\$0.9696	\$0.9696	\$0.9696
Expected volatility	45%	45%	45%
Expected option life	2.4yrs	2.7yrs	3.1yrs
Dividend yield	0%	0%	0%
Risk-free rate	1.95%	1.95%	1.95%

Note: 1. Grants to specific individuals including new starters and CEO post approval at the Annual General Meeting.

The expected volatility was determined based on historical volatility of the Company and of similar companies. The estimate reflects the likelihood that the volatility in financial markets over the next three to five years will be less extreme than that experienced during the global financial crisis and considers the likely stabilising impact of the capital raisings. The expected life of the share options is based on historical data and current expectations and is not necessarily reflective of exercise patterns that may eventuate.

NOTE 27 – PARENT ENTITY DISCLOSURES

Financial position

	2019 \$'000	2018 \$'000
Assets		
Current assets	21,278	61,961
Non-current assets	1,214,260	1,470,237
Total assets	1,235,538	1,532,198
Liabilities		
Current liabilities	4,173	2,340
Non-current liabilities	341,256	375,825
Total liabilities	345,429	378,165
Net assets	890,109	1,154,032
Equity		
Issued capital	1,140,008	1,131,761
Reserves	25,537	25,559
Accumulated losses	(275,436)	(3,288)
Total equity	890,109	1,154,032

Financial performance

	2019 \$'000	2018 \$'000
Profit/(Loss) for the year	(272,147)	32,384
Other comprehensive income	(7,184)	5,332
Total comprehensive income	(279,331)	37,716

The parent entity has written down the value of its investment in subsidiaries due to the impairments in those subsidiaries.

The parent entity has lease commitments of \$678,000 at 30 June 2019 (2018: \$686,000).

NOTE 28 – COMMITMENTS AND CONTINGENCIES

A. Commitments

Leasing commitments

The Group has operating leases on office space as well as equipment leases. Future minimum rentals payable under these operating leases are as follows:

	2019 \$'000	2018 \$'000
Within one year	2,450	3,505
After one year but not more than five years	4,445	6,107
After five years	-	-
Total minimum lease payments	6,895	9,612

Capital Commitments

The Group had \$0.5m of contractual obligations for the purchase of capital equipment as at 30 June 2019 (2018: \$2.9m).

B. Contingencies

Some Mayne Pharma companies are, and will likely continue to be, subject to various legal proceedings and investigations that arise from time to time, including proceedings regarding product liability, sales and marketing practices, commercial disputes, 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. While Mayne Pharma does not believe that any of these legal proceedings will have a material adverse effect on its financial position, 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 results of operations 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 brought against the Company seeking damages or other remedies

All these legal claims and allegations are being vigorously contested. No outcome or possible related amounts can be reliably estimated and as such no amounts have been provided at reporting date.

Drug pricing matters – investigations

In FY16, Mayne Pharma Inc received a subpoena from the Antitrust Division of the US Department of Justice and the Office of the Attorney General in the State of Connecticut seeking information relating to the marketing, pricing and sales of select generic products.

In May 2018, Mayne Pharma Inc received a Civil Investigative Demand from the Civil Division of the US Department of Justice, seeking similar information in connection with a False Claims Act investigation stemming from alleged anticompetitive conduct.

Mayne Pharma is fully cooperating with these investigations, which appear to be focused on the generic doxycycline hyclate delayed-release market, and to be part of a broader inquiry into industry practices.

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 the specific allegations related to Mayne Pharma focused on the doxycycline hyclate delayed-release market as well as allegations that all defendants were part of an overarching, industry wide conspiracy to allocate markets and fix prices generally. These cases 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, indirect purchasers and indirect resellers, as well as lawsuits filed by opt out private plaintiffs. These cases have been consolidated into multidistrict litigation pending in the Eastern District of Pennsylvania. Mayne Pharma is strongly defending the allegations made in these civil complaints.

Product liability - amiodarone

In the last few years, Mayne Pharma Inc and other pharmaceutical companies have been sued in class action complaints in California involving allegations relating to amiodarone. The issues involved include allegations of failure to adequately warn about risks associated with amiodarone, failure to provide the FDA-required medication guide, off-label promotion, and conspiring with the other defendants to downplay the risks of the drug. Mayne Pharma is vigorously defending these allegations.

Other matters

On July 9, 2019, HedgePath, LLC (HP LLC), filed a civil action involving HedgePath Pharmaceuticals, Inc. (HPPI) in the Delaware Court of Chancery. In the complaint in the action, purportedly brought directly and derivatively on behalf of HPPI, HP LLC alleges claims for breach of fiduciary duty, declaratory judgement, and dilution of stockholder equity, against HPPI's directors, former director E. Brendan Magrab, President and Chief Executive Officer Nicholas J. Virca, and Mayne Pharma Ventures Pty Ltd (a wholly owned subsidiary of Mayne Pharma International Pty Ltd) in connection with (i) the issuance of certain HPPI equity securities to Mayne Pharma Ventures on or about January 8, 2018, (ii) Mayne Pharma Ventures' alleged influence over the timing and conduct of HPPI's clinical trials of SUBA-itraconazole for the treatment of BCCNS, and (iii) amendments to a supply and license agreement between HPPI and Mayne Pharma Ventures and related transactions. The complaint also alleges claims for breach of fiduciary duty and fraudulent misrepresentation in connection with allegedly false and misleading statements. The complainant seeks unspecified damages, equitable and other relief from the defendants. HPPI has stated that it believes the action is completely without merit, and that the named director and officer defendants intend to defend themselves vigorously. Mayne Pharma Ventures is also strongly defending the allegations.

NOTE 29 – DIVIDENDS

No dividends were paid or declared in the year ended 30 June 2019 (2018: nil).

Franking credit balance

	2019 \$'000	2018 \$'000
Opening balance	24,234	23,287
Franking credits arising from payments (net of refunds)	(3,670)	1,167
Franking credits that will arise from the payment / (refunds) of income tax as at the end of the financial year	-	(5,480)
Franking credits available for future reporting periods	20,564	18,974

NOTE 30 – BUSINESS COMBINATIONS

Business combinations are accounted for using the acquisition method. The cost of an acquisition is measured as the aggregate of the consideration transferred, measured at acquisition date fair value and the amount of any non-controlling interest in the acquiree.

For each business combination, the Group policy is to measure the non-controlling interest in the acquiree at the proportionate share of the acquiree's identifiable net assets. Acquisition-related costs are expensed as incurred.

When the Group acquires a business, it assesses the financial assets and liabilities assumed for appropriate classification and designation in accordance with contractual terms, economic conditions, the Group's operating or accounting policies and other pertinent conditions as at the acquisition date.

If the business combination is achieved in stages, any previously held equity interest is remeasured at its acquisition date fair value and any resulting gain or loss is recognised in profit or loss.

Any contingent consideration to be transferred by the acquirer will be recognised at fair value at the acquisition date. Subsequent changes to fair value of the contingent consideration which is deemed to be an asset or liability will be recognised in accordance with AASB 139; *Financial Instruments Recognition and Measurement* in profit or loss.

No business combinations were undertaken during the year ended 30 June 2019 (2018: nil).

NOTE 31 – DEED OF CROSS GUARANTEE

As an entity subject to Class Order 2016/785, relief has been granted to Mayne Pharma International Pty Ltd (MPIPL) from the Corporations Act 2001 requirements for the preparation, audit and lodgement of their financial report.

As a condition of the Class Order, the Company and MPIPL entered into a Deed of Cross Guarantee on 28 June 2010. The effect of the deed is that the Company has guaranteed to pay any deficiency in the event of winding up of its controlled entity or if they do not meet their obligations under the terms of the liabilities subject to the guarantee. The controlled entity has also given a similar guarantee if the Company is wound up or if it does not meet its obligations under the terms of loans or other liabilities subject to the guarantee.

Set out below are a Consolidated Statement of Profit or Loss and Other Comprehensive Income and a summary of movements in consolidated retained earnings for the year ended 30 June 2019 of the closed group consisting of the Company and MPIPL.

(a) Consolidated Statement of Profit or Loss and Other Comprehensive Income and a summary of movements in retained earnings.

	CONSOLIDATED	
	2019 \$'000	2018 \$'000
Continuing operations		
Sale of goods	67,219	48,686
Services revenue	10,544	10,058
License fee income	1,162	-
Royalties revenue	1,250	1,172
Revenue	80,175	59,916
Cost of sales	(50,663)	(33,068)
Gross profit	29,512	26,848
Other income	70,867	73,328
Research and development expenses	(8,506)	(5,577)
Marketing expenses and distribution expenses	(4,893)	(4,410)
Amortisation expenses	(6,465)	(6,056)
Administration expenses and other expenses	(25,576)	(28,731)
Finance costs	(14,661)	(15,738)
Impairments	(304,650)	(7,995)
Profit before income tax	(264,372)	31,669
Income tax (expense)/benefit	(8,037)	(1,521)
Net profit from continuing operations after income tax	(272,409)	30,148
Other comprehensive income for the period, net of tax	(7,184)	5,332
Total comprehensive income for the period attributable to owners of the parent	(279,593)	35,480
	2019 \$'000	2018 \$'000
Retained earnings at the beginning of the financial year	120,150	82,859
Transfer from reserve	-	7,142
Profit for the period	(272,409)	30,148
Retained earnings at the end of the financial year	(152,259)	120,150

(b) Consolidated Statement of Financial Position

Set out below is a Consolidated Statement of Financial Position as at 30 June 2019 of the closed group consisting of the Company and MPIPL.

	2019 \$'000	2018 \$'000
Current assets		
Cash and cash equivalents	22,193	58,451
Trade and other receivables	8,405	6,293
Inventories	15,133	18,994
Income tax receivable	196	5,564
Other current assets	5,487	8,293
Total current assets	51,414	97,595
Non-current assets		
Related party receivables	480,765	844,249
Investment in subsidiaries	713,756	587,232
Property, plant and equipment	51,569	51,996
Deferred tax assets	6,881	4,750
Intangible assets and goodwill	72,541	80,718
Total non-current assets	1,325,512	1,568,945
Total assets	1,376,926	1,666,540
Current liabilities		
Trade and other payables	7,987	8,979
Interest-bearing loans and borrowings	14,241	-
Other financial liabilities	437	-
Provisions	5,438	4,190
Total current liabilities	28,103	13,169
Non-current liabilities		
Interest-bearing loans and borrowings	318,501	374,110
Provisions	1,116	1,113
Deferred tax liabilities	15,650	7,360
Total non-current liabilities	335,267	382,583
Total liabilities	363,370	395,752
Net assets	1,013,556	1,270,788
Equity		
Contributed equity	1,140,008	1,131,761
Reserves	25,807	18,877
Retained earnings / (accumulated losses)	(152,259)	120,150
Total equity	1,013,556	1,270,788

NOTE 32 – EVENTS SUBSEQUENT TO THE REPORTING PERIOD

No 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 Group.

NOTE 33 – NEW AND REVISED ACCOUNTING STANDARDS

In the current year, the Group has adopted all new and revised Standards and Interpretations issued by the Australian Accounting Standards Board (the AASB) that are relevant to its operations and effective for the current annual reporting period.

The adoption of these new and revised Standards and Interpretations did not have any material financial impact on the amounts recognised in the financial statements of the Group, however they may have impacted the disclosures presented in the financial statements.

At the date of authorisation of the financial report, the following relevant Standards and Interpretations were issued but not yet effective:

- (i) AASB 16 Leases (effective 1 January 2019). This Standard requires lessees to account for all leases (including operating leases) in a similar way to finance leases. At commencement of a lease, the Company will recognise a liability to make lease payments and an asset representing the right to use the underlying asset during the lease term. Depreciation of the lease asset and interest on the lease liability will be recognised over the lease term. The standard includes two recognition exceptions for leases – leases of 'low-value' assets (eg. personal computers) and short-term leases (less than 12 months). Leases will also be remeasured upon the occurrence of certain events (eg. a change in the lease term). When such events occur the lease liability and the right to use asset will be adjusted.

The Company will implement the new standard effective 1 July 2019 and will apply the modified retrospective method, with right-of-use assets measured at an amount equal to the lease liability, adjusted by the amount of the prepaid or accrued lease payments relating to those leases recognised in the balance sheet immediately before the date of the initial application and will not restate prior years.

The Company has not completed its assessment of the impact of the new standard. The Company has identified contracts relevant for the standard's application. The Group's lease commitments consist of two office leases and specific office and warehouse equipment (refer Note 28 for Operating Lease commitments as at 30 June 2019). The changes will increase amortisation, reduce operating expenses and increase interest expenses.

- (ii) AASB Interpretation 23 (effective 1 January 2019) Uncertainty over Income Tax Treatment. The Interpretation addresses the accounting for income taxes when tax treatments involve uncertainty that affects the application of AASB 112 and does not apply to taxes or levies outside the scope of AASB 112, nor does it specifically include requirements relating to interest and penalties associated with uncertain tax treatments.

The Interpretation specifically addresses the following:

- Whether an entity considers uncertain tax treatments separately
- The assumptions an entity makes about the examination of tax treatments by taxation authorities
- How an entity determines taxable profit (tax loss), tax bases, unused tax losses, unused tax credits and tax rates
- How an entity considers changes in facts and circumstances

An entity has to determine whether to consider each uncertain tax treatment separately or together with one or more other uncertain tax treatments. The approach that better predicts the resolution of the uncertainty should be followed. The interpretation is effective for annual reporting periods beginning on or after 1 January 2019, but certain transition reliefs are available. The impact of this interpretation has not been assessed.

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 Mayne Pharma Group Limited for the financial year ended 30 June 2019 are in accordance with the Corporations Act 2001, including:
 - (i) Giving a true and fair view of its financial position as at 30 June 2019 and performance for the financial year ended on that date; and
 - (ii) Complying with Accounting Standards (including the Australian Accounting Interpretations) 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.
- (c) There are reasonable grounds to believe that the members of the Closed Group identified in Note 31 will be able to meet any obligations or liabilities to which they are or may become subject, by virtue of the Deed of Cross Guarantee.
- (d) The financial statements and notes also comply with the International Financial Reporting Standards as disclosed in Note 1A.

This declaration has been made after receiving the declarations required to be made to the Directors in accordance with section 295A of the Corporations Act 2001 for the financial year ended 30 June 2019.

On behalf of the Board



Mr Scott Richards
Managing Director and CEO

Dated at Melbourne, Australia this 23rd day of August 2019.



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Independent Auditor's Report to the Members of Mayne Pharma Group Limited

Report on the Audit of the Financial Report

Opinion

We have audited the financial report of Mayne Pharma Group Limited (the Company) and its subsidiaries (collectively the Group), which comprises the consolidated statement of financial position as at 30 June 2019, the consolidated statement of profit or loss and other comprehensive income, consolidated statement of changes in equity and consolidated statement of cash flows for the year then ended, notes to the financial statements, including a summary of significant accounting policies, and the directors' declaration.

In our opinion, the accompanying financial report of the Group is in accordance with the *Corporations Act 2001*, including:

- a) giving a true and fair view of the consolidated financial position of the Group as at 30 June 2019 and of its consolidated financial performance for the year ended on that date; and
- b) complying with Australian Accounting Standards and the *Corporations Regulations 2001*.

Basis for Opinion

We conducted our audit in accordance with Australian Auditing Standards. Our responsibilities under those standards are further described in the *Auditor's Responsibilities for the Audit 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* (the Code) that are relevant to our audit of the financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Key Audit Matters

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the financial report of the current year. These matters were addressed in the context of our audit of the financial report as a whole, and in forming our opinion thereon, but we do not provide a separate opinion on these matters. For each matter below, our description of how our audit addressed the matter is provided in that context.

We have fulfilled the responsibilities described in the *Auditor's Responsibilities for the Audit of the Financial Report* section of our report, including in relation to these matters. Accordingly, our audit included the performance of procedures designed to respond to our assessment of the risks of material misstatement of the financial report. The results of our audit procedures, including the procedures performed to address the matters below, provide the basis for our audit opinion on the accompanying financial report.

Carrying value of intangible assets including goodwill

Why significant

At 30 June 2019, the Group held \$787.7 million in intangible assets including goodwill, customer contracts and relationships, product rights and intellectual property, in-process development expenditure, marketing and distribution rights and trade names. These include both finite and indefinite lived intangible assets as disclosed in Note 14 of the financial report.

At a minimum, the Group performs an annual impairment assessment of indefinite lived intangible assets and finite lived intangible assets if these are considered to display indicators of impairment. These assets are assessed either on an individual asset basis or in the Cash Generating Unit (“CGUs”) to which the assets belong.

Impairment indicators existed at 30 June 2019 in the form of below budget performance of key products within the Generics business, industry-wide generic pharmaceutical pricing pressures in the United States and the carrying amount of the Group’s net assets exceeding its market capitalisation. The range of judgments and assumptions relating to revenue growth, profit margins, research and development and overhead costs, foreign exchange and discount rates used in the Group’s impairment assessments, results in this area being considered a key audit matter.

In respect of in-process development expenditure, the range of judgments and assumptions relating to project milestone achievement, regulatory approval processes and ongoing updates of market viability of individual projects, results in this area being considered a key audit matter.

Note 14 of the financial report provides disclosure of the Group’s impairment assessments and impairment charge of \$351.7 million recognised in the current year and highlights the impact of reasonably possible changes to key assumptions as required by Australian Accounting Standards.

How our audit addressed the key audit matter

We assessed the Group’s determination of impairment indicators and whether CGUs were appropriately determined. We tested the mathematical accuracy of the Group’s value-in-use models and evaluated the assumptions and methodologies used by the Group. Where appropriate, we involved our valuation specialists to assist with the execution of these procedures.

In respect of the Group’s impairment assessment of CGUs containing indefinite and finite lived assets and in-process development expenditure, our audit procedures included the following:

- Assessed the key judgments and estimates contained within the cash flows prepared by the Group with reference to available supporting calculations and external data (where available) including revenue growth rates, profit margins and terminal growth rates.
- Assessed the current year actual results in comparison to the prior year Board approved budget to assess forecast accuracy.
- Assessed the appropriateness of the discount rates for each CGU by comparing this to external market data of comparable companies.
- In respect of capitalised in-process development expenditure:
 - assessed a sample of projects and their status against plan, including milestone achievement for the period.
 - obtained and considered any regulator correspondence for the sample of projects selected.
 - reviewed the status reports produced by the Group’s R&D Investment Committee for the period.
 - assessed any updates made by the Group to the initial project feasibility assessments.
- Considered the earnings multiples implied by the value-in-use models of each CGU against the earnings multiples of other comparable companies.
- Performed sensitivity analysis in respect of the key assumptions to ascertain the extent to which changes in those assumptions would either individually or collectively be required for the intangible assets to be impaired.

We also assessed the adequacy of disclosures made in the financial report as required by Australian Accounting Standards.

Chargebacks, rebates, returns and related accruals (“gross to net sales adjustments”)

Why significant	How our audit addressed the key audit matter
<p>In respect of the Group’s operations in the United States of America, distribution of products to its ultimate customer occurs in many cases through wholesale distributors. The ultimate net selling price is determined based on the contractual arrangements that the Group has with its indirect customers such as retail pharmacy chains and the ultimate patient’s insurer or other payment programs, whom purchase the Group’s products from the wholesale distributors.</p> <p>Revenue for products sold is recognised when control of the goods is passed upon delivery to the distributor. This requires an estimate of the variable consideration at that time, taking into consideration different elements such as chargebacks, rebates, returns and related accruals (collectively known as ‘gross-to-net’ sales adjustments). The estimate depends on customer specific contract terms and regulations, as well as customer forecast sales mix at its weighted average sales prices, trade volumes, inventories held by the distributor and historical trend of customer product returns. The dispensing of the product to the patient (being the end users) and the final determination of the actual selling price may be several months later.</p> <p>This is a significant area and a key audit matter as the estimation processes involve large volumes of data processed through the contract management system and is highly judgmental, and as such we focused our audit procedures on these ‘gross to net’ adjustments with particular focus on the gross accrual recorded at balance date and trade receivables (where chargebacks are recorded on a net basis).</p> <p>The gross accrual accounted for against revenues amounted to \$113.1 million (equivalent to US\$79.4 million) at reporting date.</p> <p>The Group’s accounting policies and significant accounting estimates for this key audit matter are disclosed in Note 2 of the financial report.</p>	<p>With respect to the contract management system that produced the underlying source data, we performed audit procedures noted below to assess the integrity and accuracy of the data.</p> <p>For each accrual we agreed the material estimates, on a sample basis, to underlying supporting documentation such as actual sales, settlements and/or reclassification between the elements of gross-to-net sales adjustments. For each of the estimated accruals, we tested the mathematical accuracy of the calculations and assessed the integrity of the data used in the calculations.</p> <p>We assessed the inputs used in the calculations including product returns, weighted average sales prices and inventory levels which remain unsold by the distributor, taking into account historical trends and specific circumstances at reporting date, to the underlying supporting documentation.</p> <p>Based on the historical data and trends our audit procedures included the following:</p> <ul style="list-style-type: none"> • Developed an expectation on expected gross to net accrual balances and compared this to the recorded accrual balances and where material variances were identified we obtained supporting evidence. • Analysed and assessed actual claims made in previous periods to evaluate the Group’s historical accuracy in estimating the gross to net sales adjustments. • Agreed a sample of transactions processed in the contract management system during the period to source documents such as signed customer contracts and claim details such as chargeback rates, product details, and wholesaler details. • Assessed claims made subsequent to balance date and considered whether these were appropriately treated at reporting date. • Analysed credit notes and payments (on a sample basis) throughout the year and post year-end, and assessed the impact to accruals recorded during the period.

Capitalisation of in-process development expenditure

Why significant

The Group held \$53.3 million in development expenditure at 30 June 2019.

The Group capitalises qualifying development expenditure on the basis that its products are generic alternatives to already proven and regulator approved, in-market original medical therapies. Where these criteria are not met, the Group expenses its research and development activities.

The capitalisation of development expenditure was considered a key audit matter as development activities are subject to uncertainties and judgmental assumptions as to the timing of regulatory approval processes and the future viability with respect to market competition of the relevant products from project initiation date to approved product launch date.

Capitalised development costs are amortised once the product is available for use, generally from when regulatory approval is obtained.

The carrying value of Capitalised Development costs are reviewed each period to identify projects no longer considered viable and impaired. The Group recorded an impairment of Capitalised Development costs of \$37.9m during the year ended 30 June 2019 as a result of this process.

Refer to Note 14 of the financial report for disclosure relating to capitalised development costs.

How our audit addressed the key audit matter

We tested the mathematical accuracy of the Group's capitalised development expenditure model and evaluated the key assumptions and methodologies used by the Group. We performed the following procedures in respect of the development expenditure capitalised:

- Assessed the nature of the costs incurred that have been assessed by Group as directly attributable to the development activities of the relevant projects, and tested the consistency of the capitalisation approach taken across the portfolio during the year and in previous periods.
- Agreed a sample of costs capitalised, including salaries and overhead costs, to timesheets and/or other supporting documentation and assessed whether these met the capitalisation criteria set out in Australian Accounting Standards.
- In respect of projects that are no longer considered viable, we determined whether the carrying amount had been appropriately written off.
- In respect of projects that have received regulatory approval, we assessed the useful life and amortisation rate allocated to these capitalised development costs with reference to the estimated future economic benefits of the assets.

We also assessed the adequacy of the related disclosures made in the financial report.

Taxation

Why significant

Accounting for tax is a key audit matter as the Group's operations are subject to income taxes in two different tax jurisdictions being Australia and the United States of America. This results in complexities around the applicability of the different tax legislations for the Group.

Additionally, as a result of the net operating loss recorded by the Group after recording a significant impairment, a deferred tax asset of \$130.7m has been recognised at 30 June 2019. An assessment of the recoverability of deferred tax assets based on tax regulatory requirements as well as future forecast profitability in both jurisdictions has been undertaken to determine the amount that may be recognised. This involves significant judgment.

The Group's disclosures are included in Note 7 of the financial report.

How our audit addressed the key audit matter

The audit procedures we performed included testing the mathematical accuracy of the Group's calculations to derive current and deferred taxes.

We involved our taxation specialists to assess the tax positions adopted by the Group for each of their material components and to assess the methodology, estimations and assumptions applied in that jurisdiction. We considered any tax regulatory restrictions applicable to deferred tax assets.

As part of these procedures we also assessed the Group's cash flow forecast, including the assumptions and estimates made to support the recognition of deferred tax assets in the current year and compared these cash flows for consistency with the Group's impairment testing.

We also assessed the adequacy of the related disclosures made in the financial report.



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Information Other than the Financial Report and Auditor's Report

The directors are responsible for the other information. The other information comprises the information included in the Company's 2019 Annual Report other than the financial report and our auditor's report thereon. We obtained the Directors' Report that is to be included in the Annual Report, prior to the date of this auditor's report, and we expect to obtain the remaining sections of the Annual Report after the date of this auditor's report.

Our opinion on the financial report does not cover the other information and we do not and will not express any form of assurance conclusion thereon, with the exception of the Remuneration Report and our related assurance opinion.

In connection with our audit of the financial report, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial report or our knowledge obtained in the audit or otherwise appears to be materially misstated.

If, based on the work we have performed on the other information obtained prior to the date of this auditor's report, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Responsibilities of the Directors for the Financial Report

The directors of the Company are responsible for the preparation of the 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 financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error.

In preparing the financial report, the directors are responsible for assessing the Group's ability to continue as a going concern, disclosing, as applicable, matters relating to going concern and using the going concern basis of accounting unless the directors either intend to liquidate the Group or to cease operations, or have no realistic alternative but to do so.

Auditor's Responsibilities for the Audit of the Financial Report

Our objectives are to obtain reasonable assurance about whether the financial report as a whole is free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with the Australian Auditing Standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of this financial report.

As part of an audit in accordance with the Australian Auditing Standards, we exercise professional judgment and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the financial report, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.

- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Group's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the directors.
- Conclude on the appropriateness of the directors' use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial report or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Group to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the financial report, including the disclosures, and whether the financial report represents the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the Group to express an opinion on the financial report. We are responsible for the direction, supervision and performance of the Group audit. We remain solely responsible for our audit opinion.

We communicate with the directors regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide the directors with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated to the directors, we determine those matters that were of most significance in the audit of the financial report of the current year and are therefore the key audit matters. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, we determine that a matter should not be communicated in our report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest benefits of such communication.



Report on the Audit of the Remuneration Report

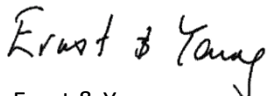
Opinion on the Remuneration Report

We have audited the Remuneration Report included in pages 15 to 21 of the directors' report for the year ended 30 June 2019.

In our opinion, the Remuneration Report of Mayne Pharma Group Limited for the year ended 30 June 2019, complies with section 300A of the *Corporations Act 2001*.

Responsibilities

The directors of the Company are responsible for the preparation and presentation of the Remuneration Report in accordance with section 300A of the *Corporations Act 2001*. Our responsibility is to express an opinion on the Remuneration Report, based on our audit conducted in accordance with Australian Auditing Standards.


Ernst & Young



David
Petersen
Partner
Melbourne
23 August 2019

INTELLECTUAL PROPERTY & GLOSSARY

Doryx®, Fabior®, Kapanol®, Lexette™, Sorilux® SUBA® and Tolsura® are trademarks of the Consolidated Entity. Bromfed®, Efudex®, Fentora®, Kapvay® and Nuvaring® are registered 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.

BA – Bioavailability. A measure of the fraction of a drug that enters the systemic blood circulation after oral administration.

BE – Bioequivalence. Two drug products are considered bioequivalent if they exhibit the "same" Cmax, Tmax and AUC in a properly powered pharmacokinetic study. In other words, the two drug products have the "same" plot of "drug concentration in plasma" against "time". The actual definition of "same" when applied to the pharmacokinetic parameters varies from country to country. If two drug products are bioequivalent, then it is assumed that they are therapeutically equivalent. A bioequivalence study is the cornerstone of an ANDA or any generic drug application, because for the reasons given here, bioequivalence obviates the need to perform long and expensive clinical studies.

DR - Delayed Release. A drug product (typically oral) that is not intended to release the drug substance immediately after ingestion. The delay is commonly related to change of pH in the gastrointestinal tract ("enteric coating") or less commonly may relate to a specific time after ingestion when the drug is released. Enteric coating is achieved by coating with polymers that are poorly soluble in low pH media (for example gastric fluid) but are soluble in media with pH values typically found lower in the intestine.

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.

PK – Pharmacokinetics. The study of the time course of the way the body handles drugs. There are four essential processes following a person's ingestion of a tablet or other oral dosage form, collectively known as ADME processes (Absorption of the drug from the gut; Distribution of the drug into other body tissues; Metabolism of the drug to other chemicals (metabolites) and Elimination of the drug from the body). This time course is typically followed by taking blood samples from volunteers at time intervals following swallowing a tablet and measuring the amount of drug and / or metabolites in the plasma. A plot can be constructed of plasma concentration against time from which various PK parameters such as Cmax, Tmax and AUC can be derived.

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