



# Mayne Pharma Group Limited

1HFY16 Results Presentation  
26 February 2016

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## Glossary

- A glossary of industry terminology is contained in the 2015 Annual Report which can be accessed at [www.maynepharma.com](http://www.maynepharma.com) and product descriptions are detailed at [www.maynepharma.com/us-products](http://www.maynepharma.com/us-products) and [www.maynepharma.com/australian-products](http://www.maynepharma.com/australian-products).

## Executive summary

### Strong financial results

- Delivered a strong financial result with revenue, EBITDA, NPAT and operating cashflow up significantly on the prior corresponding period (pcp) driven by the growth in generic products and contract services, foreign exchange benefits and the transformational Doryx™ acquisition
- Doryx™ acquisition exceeded EBITDA guidance of US\$2.7m / month over 1HFY16
- Solid financial position with flexibility to use alternate sources of capital to fund growth – gearing ratio (net debt / EBITDA) <0.3x

### Continued growth

- Accelerated investment in R&D to advance global pipeline – 18 products pending approval at FDA targeting markets with sales >US\$2bn
- Leadership team strengthened with new hires in the US and Australia
- Investment in US and Australian manufacturing sites is continuing as planned and remains on track for completion in FY18
- Business positioned to deliver strong financial growth in FY16 driven by growth opportunities across multiple channels and all business segments

# 1HFY16 key financials<sup>1</sup>

*Reported basis*

Revenue

↑ A\$127.3m, **+114%**

*Reported basis*

EBITDA

↑ A\$40.7m, **+201%**

*Reported basis*

NPAT

↑ A\$19.2m, **+380%**

*Reported basis*

Gross margin

↑ A\$80.4m, **+160%**

*Underlying basis*

EBITDA<sup>2</sup>

↑ A\$43.3m, **+197%**

*Underlying basis*

NPAT

↑ A\$20.4m, **+278%**

*Reported basis*

Gross margin %

↑ 63%, **+112bps**

*Underlying basis*

EBITDA<sup>2</sup> margin

↑ 34%, **+94bps**

*Reported basis*

Net operating cashflow

↑ A\$30.5m, **+259%**

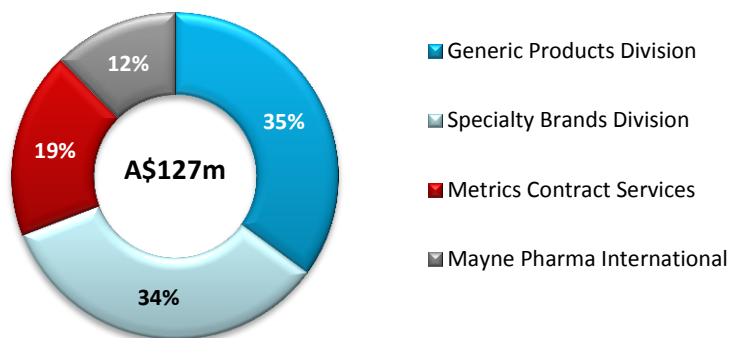
**All key performance indicators trending strongly**

- (1) EBITDA and NPAT is profit attributable to members of the Company and reconciliation of underlying NPAT is detailed in the Appendix
- (2) Adjustments to EBITDA in 1HFY16 include a A\$5.2m non-cash credit resulting from the decrease in the fair value of earn-out liabilities; A\$6.7m payment to settle a dispute with a former distributor; and A\$1.2m reflecting HedgePath Pharmaceuticals losses attributable to members of the Company.

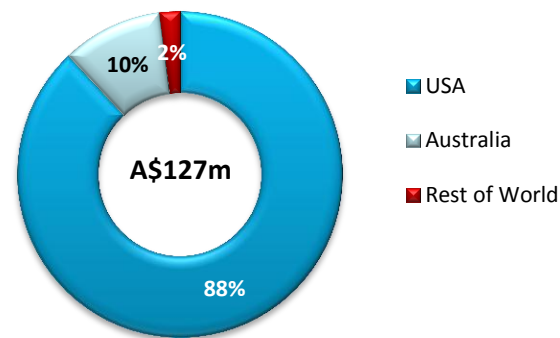
# Mayne Pharma's new segment structure

	Generic Products (GPD)	Specialty Brands (SBD)	Metrics Contract Services (MCS)	Mayne Pharma International (MPI)
<b>Description</b>	Develops, manufactures, markets and distributes generic products in the US	Markets and distributes specialty branded products in the US	Provides contract pharmaceutical development and analytical services to third party customers globally	Develops, manufactures, markets and distributes branded and generic products globally (excl. US)
<b>Strategy</b>	<ul style="list-style-type: none"> <li>Optimise market penetration of product portfolio</li> <li>Commercialise new approved products</li> <li>Control manufacture, distribution and sales and marketing of key franchises</li> </ul>	<ul style="list-style-type: none"> <li>Develop US specialty franchise by leveraging Doryx™ and pipeline of future products</li> <li>Build new specialty therapeutic platforms</li> </ul>	<ul style="list-style-type: none"> <li>Enhance operational efficiencies and client experience</li> <li>Globalise customer base</li> <li>Introduce high value manufacturing services</li> </ul>	<ul style="list-style-type: none"> <li>Commercialise growing Australian product portfolio</li> <li>Build specialty pain and injectable franchise in Australia</li> <li>Out-license Lozanoc™ and Kapanol™ in new markets</li> </ul>

## 1HFY16 Revenue by segment



## 1HFY16 Revenue by geography

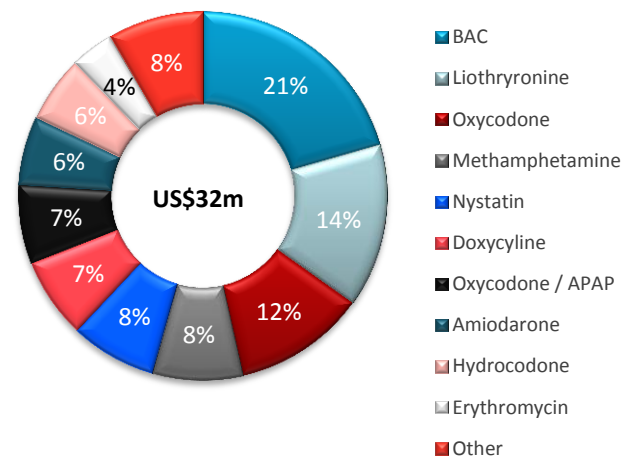


## Generic Products Division (GPD)

- GPD revenue up 33% on pcp to US\$32.3m
- Directly distributed products now represent 83% of GPD revenue up from 72% in the pcp and grew 52% on pcp to US\$26.7m driven by BAC, oxycodone, hydrocodone and methamphetamine
- 9 of the top 10 molecules grew sales versus the pcp:
  - BAC cap, methamphetamine tab, erythromycin ER tab, doxycycline ER tab and amiodarone tab have the #1 or #2 market position by volume
- BACCP cap and BAC tab launched during the half
- 3rd party generic products declined 18% to US\$5.6m reflecting the franchises that were brought in-house during FY15
- Enhanced GPD leadership and capabilities driving targeted wins
- Gross profit % declined reflecting higher sales of oxycodone and hydrocodone which participate in more competitive markets and reduced 3<sup>rd</sup> party royalties

A\$million	1HFY16	1HFY15	Change 1HFY16 v 1HFY15
Revenue	44.6	27.3	63.7%
Gross Profit	26.4	17.8	48.2%
Gross Profit %	59.1%	65.3%	

### GPD revenue breakdown

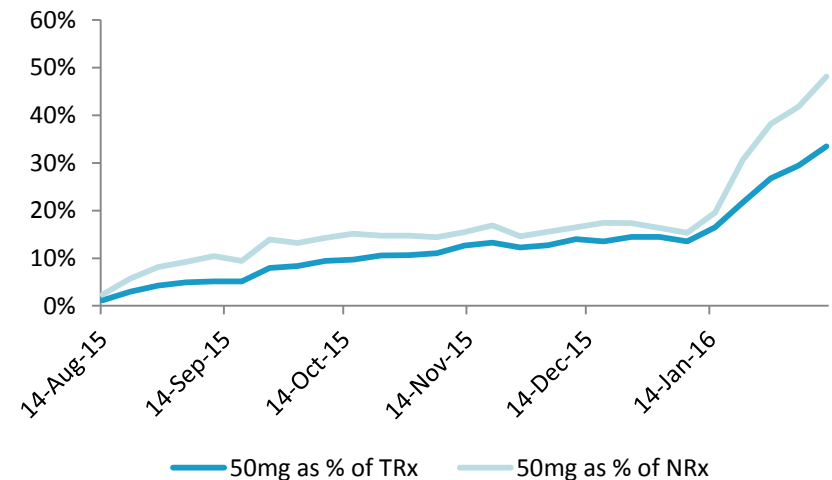


## Specialty Brands Division (SBD)

- SBD revenue was US\$31.4m for the 1HFY16
- Monthly Doryx™ EBITDA exceeded the US\$2.7m guidance given in February 2015
- Doryx™ franchise averaged >5,000 TRx / week and held onto 9% share of the tetracycline addressable market through 1HFY16
- Successful launch of the 50mg Doryx™ tablet in August 2015 with prescriptions now tracking >1,500 TRx / week in February 2016 or 33% of the total Doryx™ franchise
- Actively advancing pipeline through internal development and licensing / acquisition to grow the specialty franchise

A\$million	1HFY16	1HFY15	Change 1HFY16 v 1HFY15
Revenue	43.4	1.2	Nm
Gross Profit	38.1	1.1	Nm
Gross Profit %	87.9%	89.8%	Nm

### Doryx™ 50mg percentage of total (TRx) and new (NRx) prescriptions<sup>1</sup>



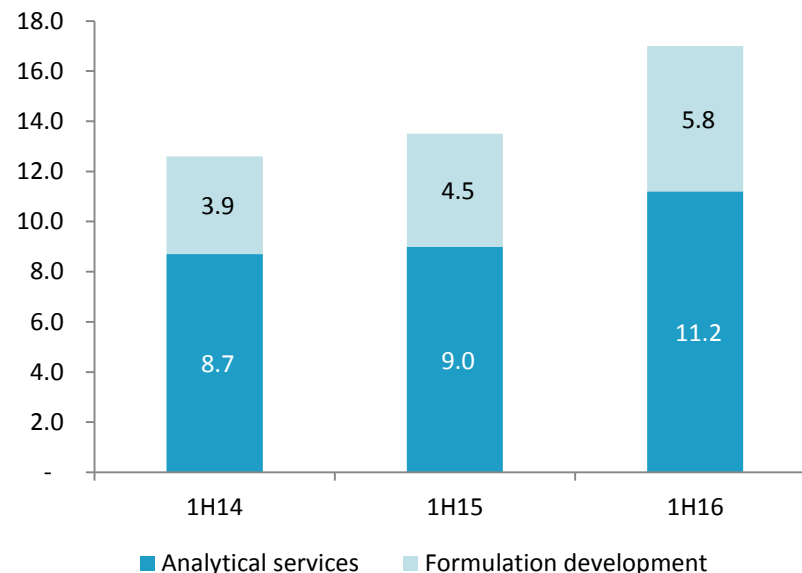
(1) IMS Health, weekly Doryx prescription volume, data up to week ending 12 February 2016

## Metrics Contract Services (MCS)

- MCS revenue was US\$17.0m up 26% on pcg benefiting from a more diversified customer base and a greater proportion of later stage, higher value development work
- Contract services market grew high single digits in 2015 driven by:
  - Expanding R&D portfolios across the pharmaceutical and biotech sector
  - Increased trend of outsourcing early stage development work particularly for advanced drug delivery technologies requiring specialised expertise
- Gross profit margin strengthened driven by price optimisation strategies and continued focus on operational efficiencies
- Key performance measures trending favourably:
  - Committed business grew 21% over 1HFY16
  - Introduced 11 new clients up from 8 in pcg
  - Average quote value won up 50% on pcg

A\$million	1HFY16	1HFY15	Change 1HFY16 v 1HFY15
Revenue	23.5	15.1	55.4%
Gross Profit	12.4	7.4	67.7%
Gross Profit %	52.6%	48.8%	

### MCS revenue by type (US\$m)



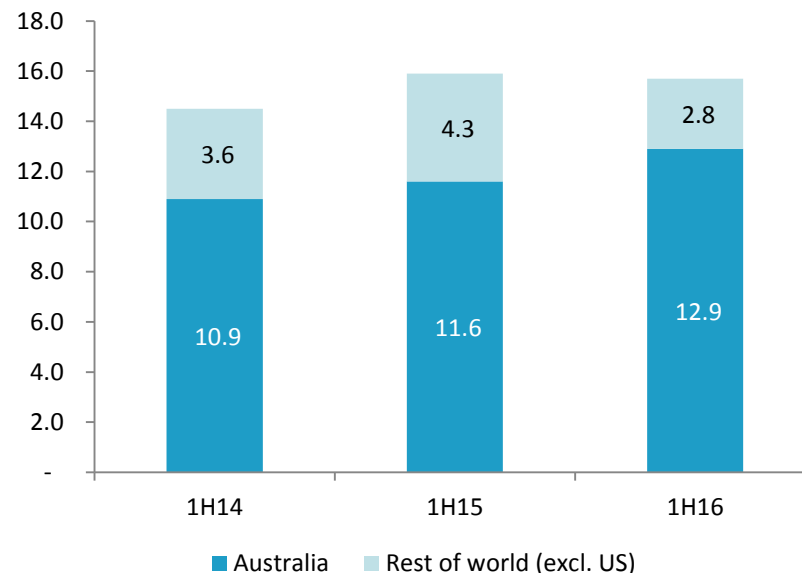


# Mayne Pharma International (MPI)

- Whilst MPI overall sales were flat, Australian sales were up 11% to A\$12.9m and international sales were down 34% to A\$2.8m
- Australian sales growth was driven by:
  - Launch of oxycodone tablet – the first independent generic to Endone
  - Expansion of hospital injectable portfolio which included 4 new launches during the half
  - OTC products such as Astrix™ capsules and Licener™
- Rest of world benefited from sales growth in the Kapanol™ and Lozanoc™ franchises but were offset by lower Astrix™ sales in Korea due to challenging market conditions which are expected to reverse in 2HFY16
- Gross profit margin decrease reflected increased pricing pressure and reduced one-off license fee income

A\$million	1HFY16	1HFY15	Change 1HFY16 v 1HFY15
Revenue	15.8	15.9	-1.0%
Gross Profit	3.5	4.7	-24.1%
Gross Profit %	22.4%	29.2%	

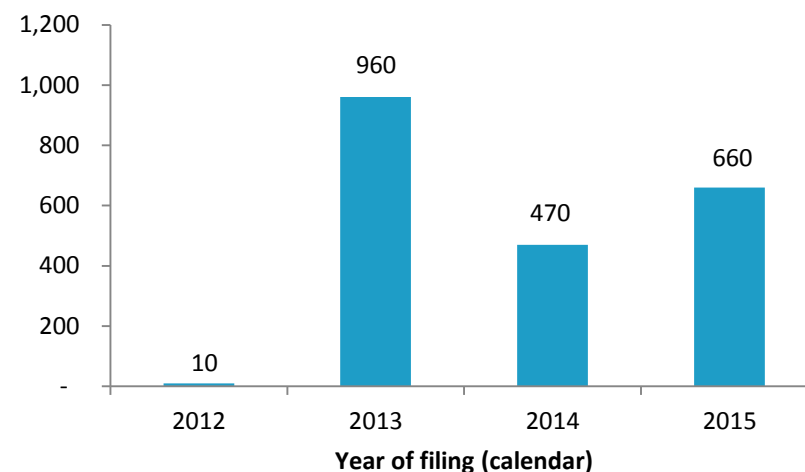
## MPI revenue by region (A\$m)



# Development pipeline expected to drive long term sustainable growth

- R&D spend was A\$14.2m up 64% on pcp as the company focused on higher value and high barrier to entry product opportunities in the US
- 35+ pipeline products in the US targeting markets >US\$7bn<sup>1</sup> including 18 products pending with FDA targeting markets >US\$2b<sup>1</sup>
  - 3 products filed with FDA during 1HFY16
  - Dofetilide – first-to-file opportunity advancing through FDA (Market size US\$183m<sup>1</sup>)
  - 7 filed products have 2016 target action dates (Market size of these products is >US\$900m<sup>1</sup>)
  - Added 5 new pipeline products during 1HFY16 targeting markets with sales >US\$600m<sup>1</sup>
- 10+ pipeline products in Australia targeting markets ~A\$100m<sup>1</sup>
  - 6 products pending with the TGA
  - Noradrenaline – first generic competitor in an A\$11m market

## Market value of US filed pipeline (US\$m)<sup>1</sup>



## US pipeline by type (number)

Orals - controlled substance	11
Orals - modified-release	10
Orals - potent	6
Semi-solid	3

## Business development activities delivering value to both on-market portfolio and pipeline

	Date	Transaction	Country	Comments
<b>On-market</b>	Feb 2015	Acquired US Doryx™ assets from Actavis	US	Exceeded earnings guidance in 1HFY16
	Mar 2015	Acquired methamphetamine tablet and BAC capsule ANDAs	US	Exceeded earnings guidance in 1HFY16
	May 2015	Acquired oxycodone franchise from Mylan	US	Total oxycodone franchise delivered US\$6m in 1HFY16 revenue
	Aug 2015	In-licensed generic BAC tablet which was launched in August 2015	US	Achieved US\$1.8m in sales in 1HFY16
	Dec 2015	Out-licensed Kapanol™ to Spirig in Switzerland	Switzerland	Opportunity to grow existing sales in US\$8m extended-release morphine market
<b>Pipeline</b>	Oct 2015	In-licensed specialty branded product	Australia	Participates in A\$24m <sup>1</sup> market
	Nov 2015	Out-licensed Lozanoc™ to ISDIN in Brazil	Brazil	6 <sup>th</sup> largest itraconazole market globally with IMS sales of US\$20m <sup>1</sup>

**Portfolio expansion targeting product and business acquisitions with attractive growth characteristics and aligned with strategic objectives**

# Outlook

<b>Generic Products Division (GPD)</b>	<ul style="list-style-type: none"> <li>• Growth in GPD driven by recent product launches, price optimisation and continued market share gains</li> <li>• Upsides will include FDA approvals and business development activity</li> </ul>
<b>Specialty Brands Division (SBD)</b>	<ul style="list-style-type: none"> <li>• SBD team has the strategies in place to protect the Doryx™ franchise in the event of generic competition on the 200mg tablet. With the SBD and GPD platforms in the US, the Company has a dual channel strategy to maximise the doxycycline franchise</li> <li>• Expect to exceed monthly earnings guidance of US\$2.7m of EBITDA on average per month during FY16</li> <li>• Actively working on pipeline through internal development and business development to expand the SBD franchise</li> </ul>
<b>Metrics Contract Services (MCS)</b>	<ul style="list-style-type: none"> <li>• MCS expected to perform strongly across FY16 with the key performance indicators such as committed business pipeline and quote dollars written and won all trending favourably</li> </ul>
<b>Mayne Pharma International (MPI)</b>	<ul style="list-style-type: none"> <li>• Australian sales expected to grow driven by injectable portfolio, oxycodone tablets and select OTC products</li> <li>• International sales expected to rebound and return to growth in 2HFY16 over 1HFY16 result</li> </ul>



# Appendix



## Earnings comparison – attributable to members

	Half year ending		Change
A\$million	31 Dec 15	31 Dec 14	\$m
Revenue	127.3	59.5	67.8
Gross profit	80.4	30.9	49.5
<i>Gross profit %</i>	63.2%	52.0%	
EBITDA - underlying	43.3	14.6	28.7
<i>EBITDA margin %</i>	34.0%	24.6%	
Adjustments	(2.6)	(1.1)	(1.5)
EBITDA - reported	40.7	13.5	27.2
Depreciation / amortisation	(10.9)	(5.0)	(5.9)
Net interest <sup>(1)</sup>	(1.4)	(2.6)	1.2
Tax	(9.2)	(2.0)	(7.2)
NPAT - reported	19.2	4.0	15.2
NPAT - underlying	20.4	5.4	15.0
Average USD:AUD FX rate	0.723	0.891	

- Gross profit margins were significantly stronger than the pcg driven by inclusion of the Doryx™ acquisition
- Underlying adjustments made to 1HFY16 EBITDA include:
  - A\$5.2m non-cash credit resulting from the decrease in the fair value of earn-out liabilities for the MPI and methamphetamine acquisitions;
  - A\$6.7m payment to settle a dispute with a former distributor; and
  - A\$1.2m being the Company's share of operating losses made by HedgePath Pharmaceuticals during the period.
- Depreciation and amortisation more than doubled reflecting amortisation of the Doryx™ brand and other intangibles
- On a constant currency basis
  - Revenue +80% on pcg
  - Reported NPAT +280% on pcg
  - Reported NPAT impact in 1HFY16 was A\$4m

(1) Includes finance expenses of \$1.2m, notional non-cash interest expense of \$0.5m less interest revenue of \$0.3m

## Balance Sheet position

	As at	As at	Change
A\$million	31 Dec 15	30 Jun 15	\$m
Cash	49.7	59.2	(9.5)
Inventory	28.6	22.4	6.2
Receivables	100.5	64.7	35.8
PP&E	65.4	59.6	5.8
Intangibles & goodwill	321.1	303.0	18.1
Other assets	35.9	20.0	15.9
<b>Total assets</b>	<b>601.2</b>	<b>528.9</b>	<b>72.3</b>
Payables	111.6	60.0	51.6
Interest-bearing debt	64.8	61.8	3.0
Other financial liabilities	13.9	34.1	(20.2)
Other liabilities	58.7	50.8	7.9
<b>Equity</b>	<b>352.2</b>	<b>322.2</b>	<b>30.0</b>
<b>Equity (attributable to shareholders)</b>	<b>341.6</b>	<b>310.9</b>	<b>30.7</b>
Net debt (bank debt less cash)	15.1	2.6	12.5
USD:AUD FX rate for translation	0.730	0.766	

- Growth in payables and receivables reflect the growing Doryx™ franchise with receivables reported on a gross sales basis
- Net debt increased by \$12.5m
  - A\$50m of cash
  - US\$47m outstanding borrowings
  - Undrawn capacity of US\$78m plus A\$10m working capital facility
- Other financial liabilities decreased by A\$20.2m reflecting:
  - A\$5.4m final payment to Hospira for the MPI acquisition in 2009;
  - A\$12.3m payments and settlements of earn-out liabilities;
  - A\$5.2m non-cash credit reflecting the decrease in the fair value of earn-out liabilities;
  - A\$0.5m notional non-cash interest charge on earn-out liabilities;
  - A\$0.7m earn-out related to US product acquisition; and
  - A\$1.5m from effects of foreign currency.

## Cash flow

	Half year ending		Change
A\$million	31 Dec 15	31 Dec 14	\$m
EBITDA - underlying	43.3	14.6	28.7
WC movements & other	1.1	(3.9)	5.0
<b>Net operating cash flow pre tax and interest</b>	<b>44.4</b>	<b>10.7</b>	<b>33.7</b>
Net interest paid	(0.8)	(1.9)	1.1
Net tax paid	(13.1)	(0.3)	(12.8)
<b>Net operating cashflow</b>	<b>30.5</b>	<b>8.5</b>	<b>22.0</b>
Capitalised R&D	(11.4)	(6.7)	(4.7)
Acquisitions	(5.2)	(0.1)	(5.1)
Capex	(6.6)	(1.5)	(5.1)
Net proceeds borrowings & shares	0.0	3.5	(3.4)
Payment of earn-out liabilities	(17.7)	(0.4)	(17.3)
<b>Net cash flow</b>	<b>(10.4)</b>	<b>3.3</b>	<b>(13.6)</b>

- Strong EBITDA to cash conversion
- Net operating cash flow pre tax and interest was A\$44.4m up A\$33.7m from 1H FY15
- Notable cashflows during the period were
  - A\$5.2m payments for US product acquisitions;
  - A\$14.2m in payments for R&D;
  - A\$17.7m in earn-out and deferred settlement payments for various acquisitions including methamphetamine, MPI acquisition and BAC; and
  - A\$6.6m in capex related to facilities expansion
- Increase in tax paid reflects increased assessable income and the timing of payments related principally to Doryx™



## Reconciliation of reported NPAT to underlying NPAT attributable to members

A\$million	1HFY16	1HFY15
NPAT - Reported	19.2	4.0
Remove impact of HedgePath	1.3	0.8
Distributor settlement	4.7	-
SBD set up costs	-	0.5
Impact of earn-out	(4.8)	0.1
<b>NPAT - Underlying</b>	<b>20.4</b>	<b>5.4</b>

# 1HFY16 Profit & Loss impact of HedgePath Pharmaceuticals

A\$million	HPPI	Mayne (excl. HedgePath)	Total
Revenue	-	127.3	127.3
EBITDA – underlying	-	43.3	43.3
EBITDA – reported	(1.2)	40.7	39.5
NPAT – underlying	-	20.4	20.4
NPAT – reported	(1.3)	19.2	17.9
Depreciation & Amortisation	(0.2)	(10.9)	(11.1)
Tax	0.1	(9.2)	(9.1)