

**FY20 Results Presentation** 21 August 2020

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#### **Non-IFRS information**

- Other than as indicated, the financial information contained in this document is directly extracted or calculated from the audited Financial Statements. Throughout this document some non-IFRS financial information is stated, excluding certain specified income and expenses. Results excluding such items are considered by the Directors to provide a meaningful basis for comparison from period to period.
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- The non-IFRS financial information has not been audited by the Group's auditors.

#### **Forward looking statements**

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#### Other

- A glossary of industry terminology is contained in the Mayne Pharma Annual Report which can be accessed at <u>maynepharma.com/investor-relations/results-reports</u> and product descriptions are detailed at <u>maynepharma.com/us-products</u> and <u>maynepharma.com/australian-products</u>.
- BALCOLTRA®, CORDRAN®, LOCOID®, LO LOESTRIN®, MONUROL®, NEXTSTELLIS™, NUVARING®, SLYND®, TAYTULLA®, TRIANEX®, UROREC® and XULANE® are registered trademarks of third parties.



### **Executive summary**

## Financial results

- Reported revenue of A\$457m, reported EBITDA of A\$80m and underlying EBITDA of A\$95m
  - Second half underlying results in line with first half and reported EBITDA up 32% on 1HFY20
- Reported net loss after tax of A\$(93)m impacted by non-cash intangible asset impairment
- Operating cash flow of A\$100m with cash conversion exceeding underlying EBITDA
- Significant opex reduction of A\$16m to optimise global infrastructure and \$15m reduction in product development spend
- Net debt reduced by A\$32m to A\$248m¹ with bank leverage ratio (net debt/EBITDA) 2.5x (versus covenant 3.5x)

## Operational highlights

- Licensed novel oral contraceptive NEXTSTELLIS™ (E4/DRSP) in the US and Australia and submitted NDA with the FDA<sup>2</sup>
- Submitted generic NUVARING® complete response letter to the FDA
- Launched four generic products and filed three generic products with the FDA including a potential first-to-market women's health product with addressable market of US\$160m<sup>3</sup>
- Generic Products performance stabilised in 2HFY20 with gross profit up 10% on 1HFY20
- Metrics Contract Services delivered solid revenue growth with sales up 15% benefiting from favourable market dynamics and new commercial manufacturing revenues
- Restructured Specialty Brands right sizing dermatology cost base

<sup>1.</sup> Excludes lease liabilities

<sup>2.</sup> NEXTSTELLIS™ trade name conditionally accepted by the FDA



## Key financials<sup>1</sup>

<b>A\$million</b>	FY20	FY19	Change
Reported revenue	457.0	525.2	(13%)
Reported gross profit <sup>2</sup>	211.5	290.9	(27%)
Reported EBITDA	80.3	111.6	(28%)
Reported net profit / (loss)	(92.8)	(279.1)	nm
Underlying EBITDA <sup>3</sup>	95.3	130.9	(27%)
Cash flow from operations	99.8	106.6	(6%)
Cash conversion <sup>4</sup>	105%	81%	

2HFY20	1HFY20	Change
229.8	227.2	1%
105.1	106.4	(1%)
45.7	34.6	32%
(75.3)	(17.5)	nm
47.9	47.4	1%
53.6	46.2	16%
112%	97%	

- EBITDA benefits from new leasing standard AASB16 by A\$4m in FY20 with A\$(0.5)m impact at bottom line
- FX benefit of A\$6m in EBITDA with average AUD:USD rate of 0.6712 in FY20 v 0.7153 in FY19
- >100% operating cash flow conversion to EBITDA

<sup>1.</sup> Attributable to members with exception of cash flow which is consolidated.

<sup>2.</sup> Gross profit calculation includes A\$14.0m depreciation in cost of sales

<sup>3.</sup> Adjustments to underlying EBITDA outlined on page 5

<sup>4.</sup> Cash flow from operations to Underlying EBITDA



## Adjustments to earnings<sup>1</sup> – FY20

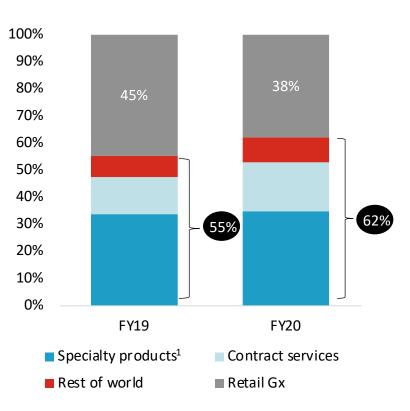
		EBIT	DA adjustme	ents	PBIT	
<b>A\$million</b>	Non cash	2HFY20	1HFY20	FY20	FY20	Comments
Reported		45.7	34.6	80.3	(102.8)	
Gross to net adjustments	Yes	5.3	9.3	14.6	14.6	Abnormal level of gross to net charges (eg. returns and govt rebates) relating to a change in accounting methodology and estimates
Inventory adjustments	Yes	3.2	1.7	4.9	4.9	Relate largely to stock writedowns on discontinued product
Impairments	Yes	-	-	-	99.0	Relate largely to generic intangibles following a detailed review of current and projected market dynamics
Earnout revaluation	Yes	(12.3)	(6.4)	(18.7)	(18.7)	Non-cash credit arising from a decrease in the fair value of earn-out liabilities
Business turnaround and restructuring	No	3.3	5.3	8.6	8.6	One-off consulting and severance costs to lower the cost base with annualised savings of US\$14m
Drug pricing investigations	No	2.0	1.2	3.2	3.2	Legal costs associated with drug pricing litigation
E4/DRSP	No	-	0.3	0.3	0.3	Transaction costs
Inhibitor Therapeutics (formerly HPPI Inc)	Part	0.8	1.4	2.2	2.7	Mayne Pharma's share of Inhibitor Therapeutics, Inc. (INTI) losses plus the fair value loss on restatement of INTI warrants
Total adjustments		2.2	12.8	15.0	114.6	
Underlying		47.9	47.4	95.3	11.7	

1. Attributable to members

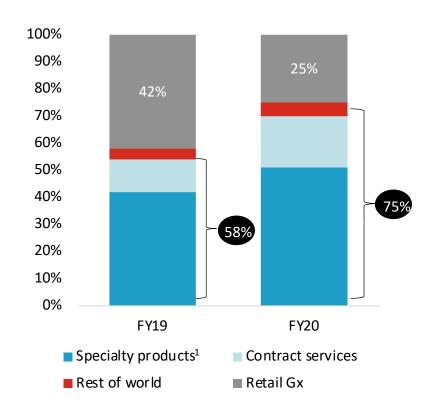


# Continued portfolio rebalancing to more sustainable therapeutic areas and segments

#### Reported revenue by type (A\$m)



#### Reported gross profit by type (A\$m)





### **COVID-19 impact**

#### **Business continuity**

- Pharmaceutical manufacturing considered an essential service
- Manufacturing sites fully operational
  - Greenville commercial dose volumes at record levels up 57% in FY20 versus pcp
  - US customer service DIFOT<sup>1</sup> 97% in FY20
- Remote working where possible and virtual engagement with customers, healthcare providers and suppliers

#### **Specialty brands**

- Limited in-person interactions with healthcare providers and less patient visits impacted new prescriptions
  - ~15% reduction in dermatology prescriptions through peak of COVID-19 lockdown due to office closures<sup>2</sup>
  - TOLSURA® impacted as infectious disease / respiratory physicians are directly involved in managing COVID-19 patients
  - Sales team utilising virtual engagement tools with prescribers where appropriate or necessary

<sup>1.</sup> Delivery in full on time



## FY21 key goals and anticipated milestones

Commercialisation of novel oral contraceptive NEXTSTELLIS™

• FDA approval and successful launch of NEXTSTELLIS™ in the US

- TGA filing of NEXTSTELLIS™ in Australia
- Recruit new women's health sales team in the US

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

- Successful launch of products pending at FDA (eg. gNUVARING®)
- Launch up to five additional women's health OCs sourced from Novast
- Continue to expand portfolio through business development activities
- Commence phase III trial using SUBA®-itraconazole in BCCNS patients and complete enrolment for phase II trial with trifarotene in lamellar ichthyosis patients

Maximise SUBA® - itraconazole franchise

- Accelerate TOLSURA® sales in FY21
- Broaden potential for therapeutic use through further clinical programs

Accelerate contract services platform globally

- Invest in new capabilities and people to accelerate growth (ie. Expansion of production space in Greenville and addition of new equipment)
- Expansion of commercial manufacturing client base in Greenville and contract development client base in Salisbury

Optimisation of cost base

- Improve cost base of contraceptive portfolio through new supply agreements
- Improve overhead recovery benefits in manufacturing plants
- Continued management of R&D and SG&A expenses



## **NEXTSTELLIS™** (E4/DRSP) a novel oral contraceptive

- Estetrol (E4) unique, native estrogen with selective action in tissues (NEST)
  - Potential to be the first new estrogen introduced in the US for contraceptive use in ~50 years
  - Potential to have a lower adverse impact on the environment
- Drospirenone (DRSP) progestin used in 9% of oral contraceptives today and known to have anti-androgenic properties<sup>1</sup>
- E4/DRSP oral contraceptive now filed in US, Europe and Canada
- Licensed by Mayne Pharma in the US and Australia

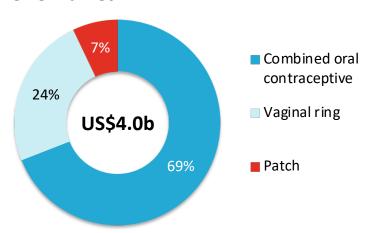


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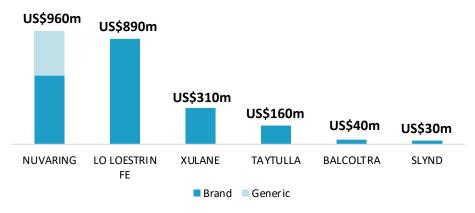


## US combined hormonal contraceptive (CHC) market

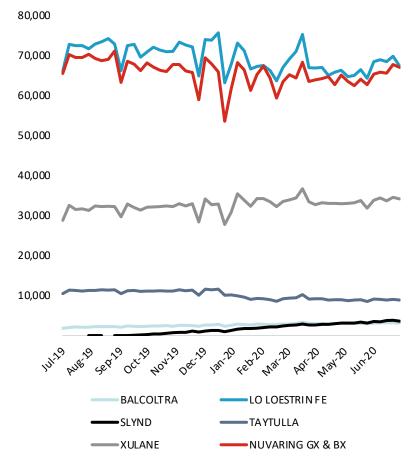
#### **CHC** market



#### **MAT sales of key CHC products**



#### CHC weekly prescriptions – select products (TRx)



Source: IQVIA, TRx and Sales, June 2020



## **NEXTSTELLIS™** (E4/DRSP) clinical trial results

- Phase 3 trials in over 3,600 women demonstrated contraceptive efficacy and safety
  - Included women with BMI 30-35 kg/m<sup>2</sup>
- There was a neutral impact on lipids and glucose in these trials<sup>1</sup>
- The women in these trials demonstrated good menstrual cycle control
- A Phase 2 trial showed a lower effect than another DRSP containing oral contraceptives on certain markers of coagulation<sup>1,2</sup>





## **NEXTSTELLIS™** (E4/DRSP) oral contraceptive update

#### Regulatory

- NDA accepted for filing with potential approval and launch 2QCY21
- TGA filing CY20 with potential approval 2HCY21
- NEXTSTELLIS™ brand name received conditional acceptance from FDA

## Medical / Commercial

- Medical Science Liaison team in place for scientific exchange with healthcare professionals
- US launch to be supported by new women's health sales force (~80 in field professionals), medical affairs, marketing and administration support
  - District manager and sales team recruitment in quarter prior to launch
  - Focus on 14,000 high-prescribing OBGYNs
- Consumer marketing campaign being developed



# Expanding dermatology and women's health portfolio and advance key pipeline products

### **Dermatology**

- Launched gCORDRAN®, gLOCOID® and gTRIANEX® in FY20
- Licensed topical acne product which is pending at the FDA targeting addressable market of US\$40m<sup>1</sup>
- Two high impact rare disease skin programs in development
  - SUBA-itraconazole to treat BCCNS / Gorlin's Syndrome going into phase III in FY21
  - Trifarotene to treat lamellar ichthyosis currently in phase II

#### Women's health

- Licensed novel oral contraceptive, NEXTSTELLIS™ to launch in US and Australia and submitted NDA with the FDA
- Filed complete response letter for gNUVARING® with FDA
- Filed potential first-to-market contraceptive product with FDA targeting addressable market of US\$160m<sup>1</sup>
- Entered into long-term supply agreement with Novast Laboratories for 13 oral contraceptive products, including 5 products not previously marketed by the Company targeting addressable markets of US\$500m<sup>1</sup>

Continue to assess business development opportunities to expand portfolio in complementary indications with favourable market access dynamics

1. IQVIA MAT Sales, June 2020



# Dermatology and women's health pipeline market potential

Product	Indication	Mkt size (US\$m)¹	Bx / Gx	Phase II	Phase III	Filed	Approved
Dermatology							
SUBA®-itraconazole	BCCNS	300	Вх				
Trifarotene	Lamellar ichthyosis	200	Вх	-			
Gx topical	Acne	40	Gx			-	
Women's health							
NEXTSTELLIS™ - US	Contraception	4,000	Вх			-	
NEXTSTELLIS™ - AU	Contraception	50	Вх				
gNUVARING®	Contraception	960	Gx			-	
Gx oral solid	Contraception	160	Gx			-	
5x generic OCs (Novast)	Contraception	500	Gx				-

~US\$6b near to mid term addressable market potential in dermatology and women's health

<sup>1.</sup> Total addressable market based on IQVIA sales data as at Jun 2020 for generic products and target patient population, pricing and current healthcare costs to treat patient population used to determine brand products



## Trifarotene – a retinoid for lamellar ichthyosis

- Lamellar ichthyosis is a rare dermatological disorder with high unmet medical need
  - Begins at birth and causes severe skin scaling
- Trifarotene, a retinoic acid receptor-y (RARy) agonist, is being studied for this indication
- Granted Orphan Drug Designation in US / EU
  - 7 years exclusivity in the US; 10 years in Europe from approval
- Global phase II study in approximately 120 patients with lamellar ichthyosis has commenced
  - Randomised, multi-center, double-blind, placebo controlled study
  - 26 patients now on study
  - Top line results expected end FY21
- Global market potential US\$200m<sup>1</sup>



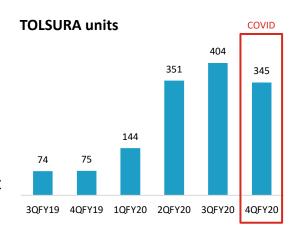




#### Maximise SUBA®-itraconazole franchise

Anti-fungal (TOLSURA®)

- TOLSURA® experienced solid growth across
   FY20 until the 4QFY20 / COVID-19 pandemic
- Endemic mycoses study interim results to be presented at IDWeek in October 2020
- New studies as treatment for coccidioidomycosis infections and as prophylaxis in lung transplant patients to start in 1HFY21



Basal Cell Carcinoma Nevus Syndrome (BCCNS or Gorlin Syndrome)

- Phase IIb trial in 38 BCCNS patients with SUBA®-itraconazole showed positive effects
- Mayne Pharma expected to commence a phase III trial in BCCNS patients in FY21 following end of phase II meeting with the FDA

**Oncology** 

- Itraconazole has notable anti-cancer effects through inhibition of the Hedgehog signalling pathway
- A number of exploratory clinical studies have been completed or under recruitment by third parties using itraconazole in BCC, lung, prostate and ovarian cancer patients

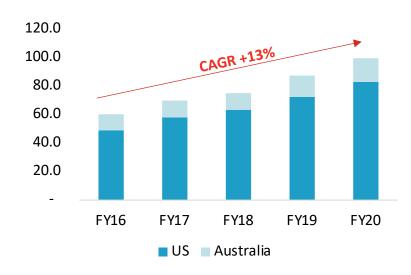


## Accelerate contract service platform globally

#### **Key facts**

- 170+ analytical chemists and formulators
- 100+ active clients
- Support 14 of the top 20 global pharma companies<sup>1</sup>
- >40 years of history in contract services in Australia and
   >25 years in the US
- Expertise in oral solid and topical dose forms including high potent compounds

#### Contract services historical sales (A\$m)



- Contract services and manufacturing represented 21% of FY20 group revenue or ~A\$100m
- Strong track record of growth over time driven by expansion of facilities and new head count
  - Appointed head of contract services in Australia to drive new business
  - Expansion of US team in FY20 to support committed pipeline
- Expansionary capex investments in FY21 of ~A\$15m to enhance capacity offering and support planned commercial manufacturing growth in the US and Australia



### **Optimisation of cost base**

FY20 achievements

- Reduced global workforce by approximately 10% across FY20
- Discontinued unprofitable generic SKUs
- Opex reduced by A\$16m in FY20 versus pcp
- Streamlined generic R&D and reduced gross spend by A\$15m in FY20 versus pcp

**Future** 

- Expected dermatology opex savings of US\$7m in FY21 to improve profitability
- NEXTSTELLIS™ launch costs in FY21 estimated to be US\$20m with US\$3m in 1HFY21 covering build out of sales force, medical education and marketing activities based on April 2021 PDUFA date
  - Operating expenses expected to be ~25% of peak net sales
- Cost savings in future periods are expected to be largely in COGS eg.
   API savings, overhead recovery benefits from product transfers in house and cost savings from transfers to new contract manufacturers



FY20 segment and financial information

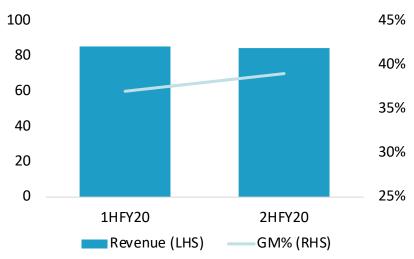


## **Generic Products Division (GPD)**

- In USD terms, GPD reported revenue was US\$169.8m, down 26% on pcp impacted by competition on key products - liothyronine, dofetilide and butalbital
- FY20 also impacted by abnormal gross-to-net charges of A\$15m and stock writedowns largely relating to discontinued stock of A\$5m that are not expected to repeat in FY21
  - Adjusted gross margin excluding abnormal items would have been 43%
- More diverse portfolio with largest product liothyronine representing 11% of revenue down from 19% in the pcp
- 2HFY20 reported gross profit up 10% on 1HFY20 benefiting from product transfers into Greenville and Salisbury and reduced stock obsolescence

A\$million	FY20	FY19	Change FY20 v FY19
Reported revenue	253.0	320.8	(21%)
Gross Profit	95.7	164.5	(42%)
Gross Profit %	38%	51%	

#### GPD reported performance by half (US\$m)

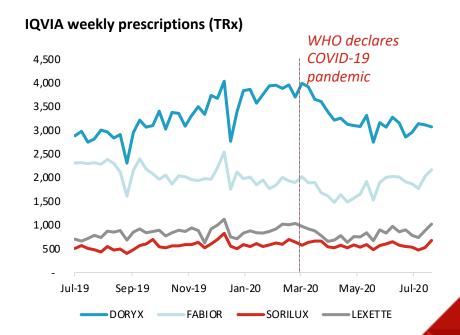




## **Specialty Brands Division (SBD)**

- In USD terms, SBD revenue was US\$52.9m, down 19% on FY19
- DORYX®, FABIOR® and SORILUX® sales were down on pcp impacted by COVID-19, tightened managed care and new competitor launches
  - TRx volumes down ~15% and NRx volumes down ~30% during peak of COVID-19 lockdown<sup>1</sup>
- LEXETTE® and TOLSURA® contributed to growth year on year
- Restructured dermatology sales team which is expected to deliver US\$12m of annualised savings with US\$5m achieved in FY20

<b>A\$million</b>	FY20	FY19	Change FY20 v FY19
Reported revenue	78.8	91.6	(14%)
Gross Profit	65.4	79.8	(18%)
Gross Profit %	83%	87%	



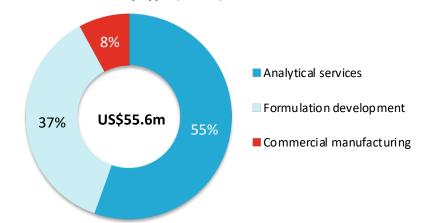


### **Metrics Contract Services (MCS)**

- In USD terms, MCS revenue was US\$55.6m, up 8% on pcp benefiting from new development programs and manufacturing revenues
- Quotes US\$ won increased 8% in FY20 versus FY19
- MCS has 5 commercial manufacturing clients up from 1 at the end of FY18
- Commercial manufacturing represents 8% of MCS revenue and grew 50% on pcp
- MCS has executed global supply agreements with two top 10 pharma companies
- Over time, MCS expects to transition more of its development clients into full service clients utilising services from formulation development and analytical services through to commercial manufacturing

A\$million	FY20	FY19	Change FY20 v FY19
Reported revenue	82.8	72.2	15%
Gross Profit	39.4	35.5	11%
Gross Profit %	48%	49%	

#### MCS FY20 revenue by type (US\$m)



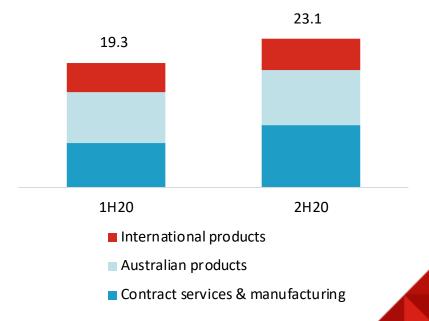


## **Mayne Pharma International (MPI)**

- MPI performance was significantly stronger in the 2HFY20 with sales up 20% on 1HFY20 benefiting from positive impacts of COVID-19
- In Australia, specialty products UROREC® and MONUROL® contributed to growth year on year
- UROREC (silodosin) capsules was added to the Australian Government Veteran's reimbursement program (RPBS)
- Contract services revenue increased 11% on pcp and benefited from additional formulation development projects and increased manufacturing revenues
  - Appointed head of contract services in Australia to drive new business
  - 6 active contract service projects up from 2 in the pcp

<b>A\$million</b>	FY20	FY19	Change FY20 v FY19
Reported revenue	42.4	40.7	4%
Gross Profit	11.0	11.0	0%
Gross Profit %	26%	27%	

#### MPI sales by type (A\$m)





## Significant reduction in R&D and operating expenses

#### R&D spend<sup>1</sup>

<b>A\$million</b>	FY20	FY19	Change FY20 v FY19
R&D expensed	24.8	28.5	(13%)
R&D capitalised	11.0	21.8	(50%)
Total R&D	35.8	50.3	(29%)
R&D capitalisation rate	31%	43%	
R&D as % revenue	8%	10%	

- Generic R&D spend reduced by ~50% yoy
- >75% of R&D spend directed to key therapeutic areas of dermatology, women's health and infectious disease

#### Operating expenses<sup>1</sup>

<b>A\$million</b>	FY20	FY19	Change FY20 v FY19
Marketing & distn	74.2	82.0	(10%)
All other admin <sup>2</sup>	54.8	63.3	(13%)
Total opex expenses	129.0	145.3	(11%)

- Opex expenses benefited from the restructure to further right size organisation and optimise global infrastructure
- AASB16 has not materially impacted opex expense as operating lease cost of A\$4.4m now treated as depreciation in the same expense line

<sup>1. 100%</sup> consolidated. Depreciation included in R&D expense (A\$3.0m), marketing & distribution (A\$1.8m) and all other admin (A\$2.7m)

<sup>2.</sup> Refer to 'All other administration and other expenses' in note 4 of the Financial Statements. Excludes non-cash items and adjustments to underlying earnings



# Reported to underlying earnings attributable to members

A\$million	Reported FY20	Earn-out reassessment		Impairment	Drug pricing investigations	INTI	Gross-to-net adjustment		E/1/11250	Underlying FY20
Revenue	457.0						14.6			471.6
Gross profit	211.5						14.6	4.9		231.0
Gross profit %	46%									49%
EBITDA	80.3	(18.7)	8.6		3.2	2.2	14.6	4.9	0.3	95.3
Depreciation / Amortisation	(84.1)					0.5				(83.6)
Impairments	(99.0)			99.0						-
PBIT	(102.8)	(18.7)	8.6	99.0	3.2	2.7	14.6	4.9	0.3	11.7



## **Consolidated balance sheet position**

		Pre AASB16	
<b>A\$million</b>	As at 30 Jun 20	As at 30 Jun 20	As at 30 Jun 19
Cash	137.8	137.8	89.0
Inventory	94.0	94.0	100.3
Receivables	195.9	195.8	256.6
PP&E	226.4	226.4	236.0
Intangibles & goodwill	962.3	962.3	797.6
Right of use assets	11.9	-	-
Other assets	197.0	197.0	156.2
Total assets	1,825.2	1,813.3	1,635.7
Payables	106.9	106.9	129.9
Borrowings	398.0	385.6	369.4
Other financial liabilities	233.0	233.0	73.9
Other liabilities	45.0	45.0	49.0
Equity	1,042.3	1,042.8	1,013.5
Equity (attributable to members)	1,037.5	1,038.0	1,007.2
AUD:USD FX rate	0.6877	0.6877	0.7022
Net debt	260.2	247.9	280.4

- Growth in intangibles and financial liabilities reflects inclusion of NEXTSTELLIS™
  - Unwind of the discount on the NEXTSTELLIS™ earnout liabilities which appears in finance expense is estimated to be US\$11m in FY21
- Increase in borrowings due to new leasing standard AASB16 and FX
- Reduced balance sheet gearing with net debt down A\$32.5m excluding lease liabilities



## Consolidated cash flow – EBITDA to cash reconciliation

	Full Year ending	
A\$million	30 Jun 20	30 Jun 19
Reported EBITDA attributable to members <sup>1</sup>	80.3	111.6
Minority share of INTI EBITDA	(1.4)	(2.6)
Consolidated EBITDA (100% INTI)	78.9	109.0
Share based payments (non cash)	7.0	9.0
INTI warrants fair value (non cash)	0.6	8.2
Movement in earn-outs (non cash)	(18.7)	5.5
Provisions (non cash)	(2.9)	(7.3)
Other	(0.7)	3.8
Operating Cash flow Before WC, interest and tax	64.2	128.2
WC movements	50.2	(29.1)
Net tax (paid) / received	(1.8)	21.0
Net interest paid	(12.8)	(13.5)
Net operating cash flow	99.8	106.6
Capitalised R&D	(11.0)	(21.8)
Acquisitions	(27.1)	(48.7)
Capex	(9.0)	(11.9)
Earn-out & deferred settlement payments	(8.8)	(9.3)
Free cash flow	43.9	14.9
Net proceeds borrowings & shares	4.5	(15.5)
Net cash flow	48.4	(0.6)

 Cash flow working capital movements based on average AUD/USD exchange rate for the period whereas the June balance sheet balances based on closing rates



## **Capital structure**

- Company has A\$138m of cash and A\$200m of undrawn debt
- Dual currency debt facility
  - US\$150m, 3 year bullet facility, matures December 2021
  - US\$200m, 5 year revolving facility, matures December 2023
  - US\$50m, 364 days receivables financing facility (non-recourse facility), matures December 2020
  - US\$20m, 2 year working capital facility, matures
     November 2021
  - A\$10m, 2 year working capital facility, matures November 2021
- Key bank covenants have significant headroom:

Financial metrics	As at 30 Jun 20	As at 30 Jun 19
<b>Leverage ratio:</b> Net financial debt <sup>1</sup> / EBITDA Covenant <3.5x	2.5x	2.0x
Interest cover ratio: EBITDA / interest Covenant >3x	6.5x	8.4x
Shareholders funds Covenant > A\$700m	A\$1.0b	A\$1.0b

#### **Net debt**

A\$million	As at 30 Jun 20	As at 30 Jun 19	Change
Syndicated facility	344.4	332.7	11.7
Receivables financing	41.2	36.6	4.6
Lease liabilities	12.4	0.0	12.4
Borrowings	398.0	369.4	28.6
Cash	137.8	89.0	48.8
Net debt (excl. lease liabilities)	247.9	280.4	(32.5)