



PALLA PHARMA

# INVESTOR UPDATE

30 September 2021

ASX: PAL



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# 1H21 FINANCIAL RESULTS



# 1H21 RESULTS OVERVIEW

## *Gross Profit contribution impacted by delay in UK regulatory approval of Marketing Authorisation products*

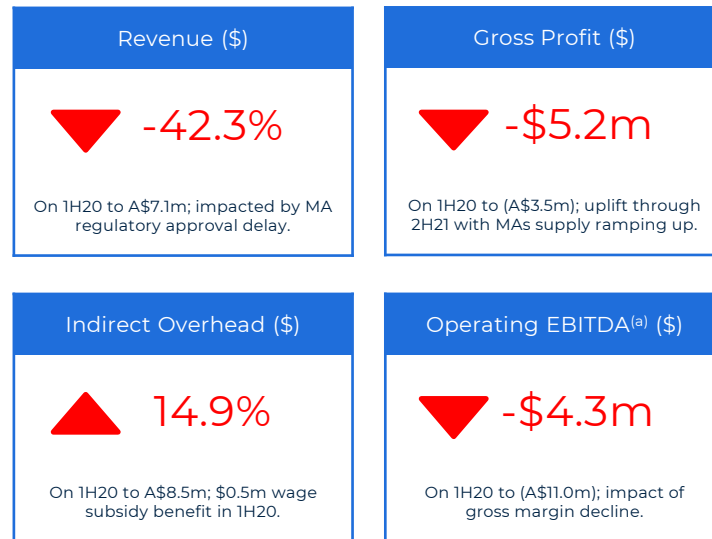
Revenue impacted by delayed launch of Marketing Authorisation (MA) Finished Dosage (FD) products due to unanticipated regulatory delays; revenue to accelerate in 2H21 from sales of opiate based MA products

Gross Profit lower due to reduced revenue and manufacturing inefficiencies associated with reduced production volumes and the timing of the planned early exit from the legacy non-opiate based FD supply agreement intended to free up production capacity for the new MA products

Indirect Overhead costs increased due to additional Norway headcount required to support MA product launch in the UK and the prior period \$0.5m in wage subsidy receipts

Operating EBITDA<sup>(a&b)</sup> impacted by the decline in revenue and lower Gross Profit contribution

Net debt has reduced as a result of the equity capital raising of \$16.9m completed in March 2021



(a) Operating EBITDA is a non-GAAP financial measure – see appendix for reconciliation of Operating EBITDA to statutory net profit/(loss) after tax.

(b) The unaudited 1H21 preliminary interim financial report was lodged with the ASX Appendix 4D on 31 August 2021. The auditor reviewed 1H21 interim financial report was lodged with ASX on 30 September 2021, in compliance with the COVID extended reporting timetable. The auditor reviewed financial statements are substantially the same as the financial statements previously lodged with the ASX, other than some updated wording changes in the Review of Operations note 1(c) Going Concern Note and other related notes.



# TRADING RESULTS SUMMARY

## Revenue impacted by delays in UK regulatory approvals of Marketing Authorisation products

A\$ million	1H21	1H20	Change %	
<u>Revenue by Business Unit:</u>				
NRM & Seed	0.9	2.5	↓ 64.0%	• FD revenue impacted by delay in launch of MA products due to unanticipated delay in manufacturing site change and packaging regulatory approvals in the UK
API	4.5	6.0	↓ 25.0%	• Reduced poppy seed revenue following reduction in domestic harvest growing area
Finished Dosage	1.7	3.8	↓ 55.3%	• Reduced API sales due to reduced codeine phosphate demand from COVID-19 measures introduced in key European markets delaying elective surgeries
<b>Total Revenue</b>	<b>7.1</b>	<b>12.3</b>	↓ 42.3%	• Manufacturing inefficiencies experienced as a result of lower API production volumes and delay in MA product launch impacted Gross Profit contribution
Gross profit	(3.5)	1.7	nm	• Credit loss provision reversal due to recovery of long outstanding debtor
Gross margin (%)	(49.7%)	14.0%	nm	• Significant items include impairment of inventory (\$11.5m) and impairment of non-financial assets (\$8.2m)
Credit loss provision	(1.1)	1.1	nm	
Indirect overhead	8.6	7.3	↑ 17.8%	
<b>Operating EBITDA<sup>(a)</sup></b>	<b>(11.0)</b>	<b>(6.7)</b>	nm	
Significant items	(19.9)	(0.1)	nm	
Reported EBITDA	(30.9)	(6.6)	nm	

(a) Operating EBITDA is a non-GAAP financial measure – see appendix for reconciliation of Operating EBITDA to statutory net profit/(loss) after tax.



# INCOME STATEMENT SUMMARY

## *Underlying EBIT and Net Loss impacted by reduced gross profit contribution*

A\$ million	1H21	1H20	Change \$
Reported EBITDA	(30.9)	(6.6)	(24.3)
Depreciation and amortisation	1.3	1.4	(0.1)
Reported EBIT	(32.2)	(8.0)	(24.2)
<b>Underlying EBIT (before significant items shown below)</b>	<b>(12.3)</b>	<b>(8.1)</b>	<b>(4.2)</b>
Net finance expenses	(0.9)	(1.0)	0.1
<b>Net Profit/(Loss) (before significant items shown below)</b>	<b>(13.2)</b>	<b>(9.1)</b>	<b>(4.1)</b>
Significant items	(19.9)	0.1	(20.0)
<b>Reported Net Profit/(Loss)</b>	<b>(33.1)</b>	<b>(9.0)</b>	<b>(24.1)</b>

- Underlying EBIT (EBIT before significant items) impacted by reduced gross profit contribution from reduced sales volume
- Reported Net Loss increased compared to the prior corresponding period due to reduced gross profit contribution

# CAPITAL EMPLOYED SUMMARY

*Net working capital reduction; reduced net debt due to March 2021 equity capital raising*

A\$ million	Jun 2021	Dec 2020	Change \$	
Trade & other receivables	4.8	8.3	(3.5)	• Trade & other receivables reduced due to reduced sales revenue
Contract assets	0.2	0.8	(0.6)	• Contract assets reduced due to lower CMO supply agreement volumes
Inventories				• Raw materials inventory increased from December due to domestic straw harvest timing
- Raw materials	10.5	5.9	4.6	
- Work in progress	8.8	20.5	(11.7)	• Work in progress inventory reduced due to a modification in NRM production process requiring an increase to the inventory obsolescence provision
- Finished goods	5.8	2.7	3.1	
<b>Total inventories</b>	<b>25.1</b>	<b>29.1</b>	<b>(4.0)</b>	
Trade & other payables, provisions	(14.3)	(12.8)	(1.5)	• Finished goods inventory increased due to MA product launch and inventory build at UK distributor
<b>Net working capital</b>	<b>15.8</b>	<b>25.5</b>	<b>(9.7)</b>	
Cash	0.9	0.6	0.3	• Net debt has reduced as a result of the equity capital raising having been completed in March 2021
Borrowings	15.0	18.0	(3.0)	
<b>Net debt</b>	<b>14.1</b>	<b>17.4</b>	<b>(3.3)</b>	



# TRADING UPDATE

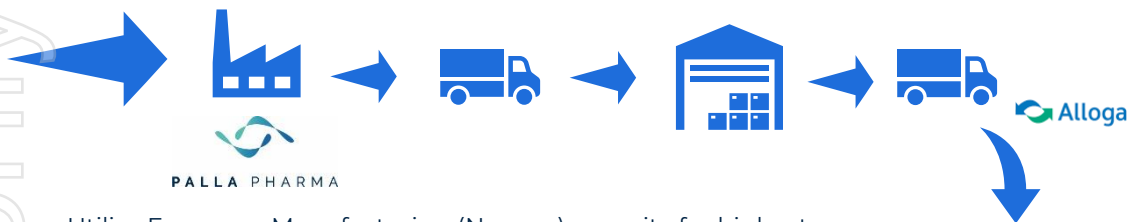
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# ROUTE TO MARKET FOR OWNED MA PORTFOLIO

*Multi-source UK customer supply model established through use of internal and CMO manufacturing capacity*

## Multi-source UK Customer Supply Model



- Utilise European Manufacturing (Norway) capacity for highest volume and value Codeine Phosphate products; deliver direct to 3PL logistics partner in the UK with extensive supply network of wholesalers and distributors who then supply direct to UK customer base
- Contract Manufacturing Organisation (CMO) partnership established with UK based M&A Pharmachem to provide UK Manufacturing capacity for Codeine Phosphate products and accelerate UK market entry for remaining MA's



## MA products launched 2021

1. 30/500mg  
Codeine Phosphate/Paracetamol Caplet
2. 30/500mg  
Codeine Phosphate/Paracetamol Tablet

## Other MAs acquired in 2020

1. 8/500mg  
Codeine Phosphate/Paracetamol Tablet
2. 10/500mg  
Dihydrocodeine /Paracetamol Tablet
3. 20/500mg  
Dihydrocodeine / Paracetamol Tablet
4. 30/500mg  
Dihydrocodeine / Paracetamol Tablet
5. 30mg Dihydrocodeine Tablets

# MANUFACTURING AND VALUE CREATION

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*Manufacturing footprint to be optimised in 2022 as additional product regulatory approvals are received*

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European Manufacturing (Norway):

- API capacity of 70t to supply both internal and CMO Finished Dosage requirements
  - Finished Dosage capacity of 750,000 packs per month, **currently running at 550,000 packs per month**
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UK Manufacturing:

- Partnership with M&A Pharmachem to provide additional Finished Dosage capacity
  - 200,000 packs equivalent per month, **significantly increasing options in 2022**
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Product approvals pending:

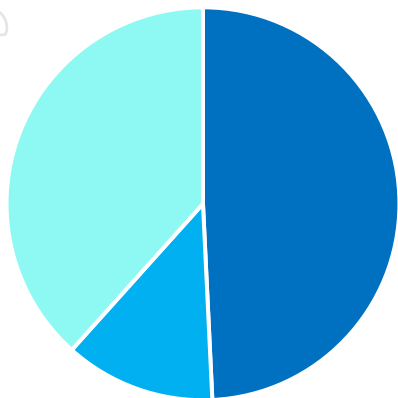
- 10/500 Co-Dydramol Tablets (Cartons) - UK
  - Dihydrocodeine Tablets (Cartons) – UK
  - 30/500 Co-Codamol Tablets / Caplets (Cartons) - Europe
- 



# SALES & DISTRIBUTION PROGRESS

*Palla is qualified with 8 of the 12 largest wholesalers in the UK market*

## Major Wholesaler Outlets



- Nationals 100+
- 6+ Pharmacy Groups
- 1-5 Pharmacy Groups

- ~50% of total Pharmacies are Nationals
- Supermarkets represent around 10% of total Nationals
- Major Wholesalers purchase over 12m packs of Co-Codamol 30/500 per year

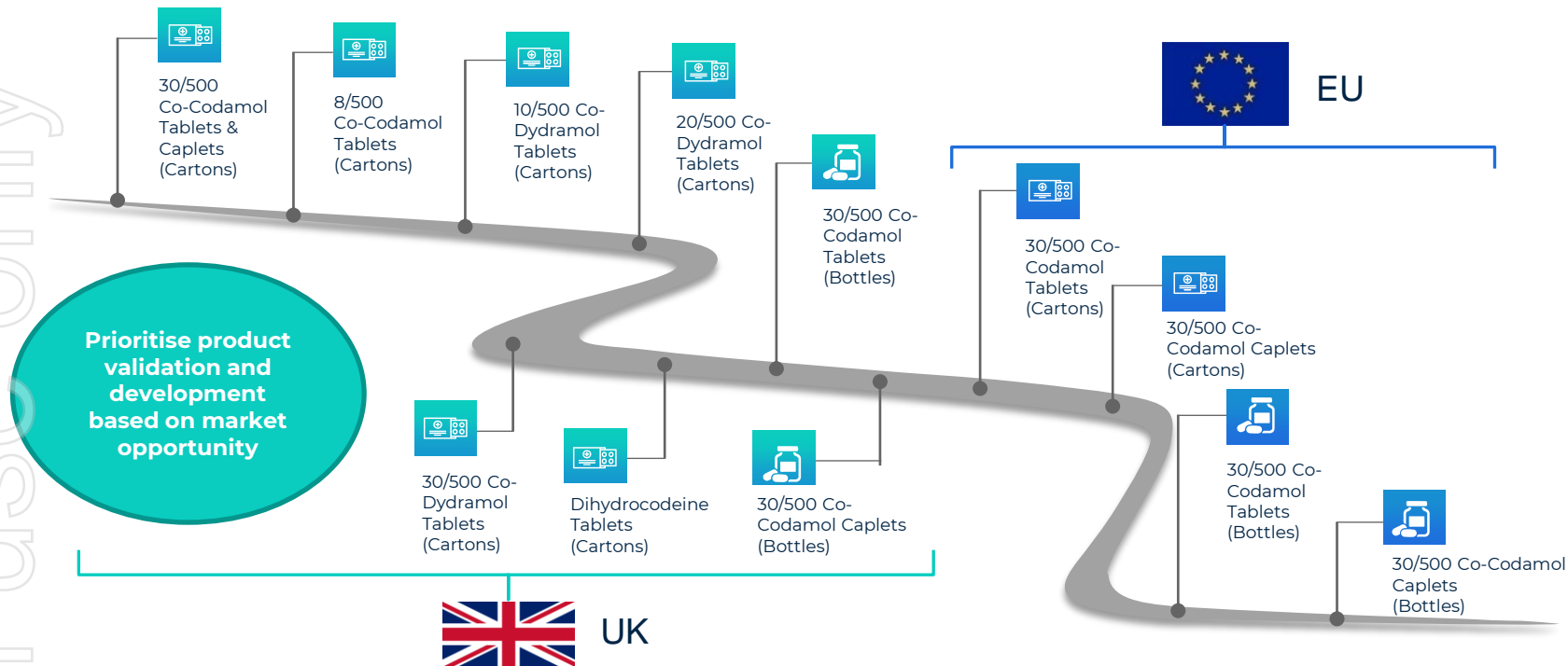
- Currently supplying to 5, which together supply ~70% of the UK Co-Codamol 30/500 retail market
- By the end of 2021 expect to be qualified and supplying to almost all major wholesaler customers
- Recent agreement reached to enter the branded segment of the pain market servicing Clinical Commissioning Groups (CCGs) – expanding the total accessible market by up to 36% (360k packs pm)

Source: GPC 2016



# PRODUCT ROAD MAP: 2021 to 2023 – UK and EUROPE

*Product Roadmap to drive maximum value from acquired MA's*



# UK PRODUCT SALES UNDERWAY WITH EUROPE NEXT

*Owned Marketing Authorisation products selling in the UK with regulatory process set to add Europe*

Following final MHRA approval in March, the European Manufacturing facility (Norway) commenced manufacture of the 2 highest value and volume MA products

As part of the pan-European launch EU, approval has been sought from the Irish and German regulators for Co-Codamol products with approval anticipated in H2 2022

To support distribution Palla has appointed Alloga as a third party distribution partner for logistics and supply chain services

The Contract Manufacturing Partnership with M&A Pharmachem creates Palla's UK Manufacturing base to maximise the production from owned MA licenses, further CMO opportunities and API supply

First Palla Pharma Co-Codamol 30/500mg Tablets lifted from the packing line by robotic lifter (21 March 2021)



# BUILDING BLOCKS IN PLACE FOR NEXT PHASE OF GROWTH

*With major strategic milestones achieved in 2020 & 2021, the focus remains on execution*

Rate of production is consistently meeting planned expectations at the European Manufacturing base in Norway following an initial period of recalibration

Core 30/500 Co-Codamol caplet and tablet product approval received in February 2021 with product launch and first sales commencing in Q2 2021

Demand is building with the sales team active in the market with key customers, despite challenges posed by Covid 19. Initial response has been positive with progress being made in September

Following a successful production period, the necessary inventory levels have been built to support sales execution through this year

The addition of a new CEO, with extensive experience in sales and marketing, will assist the development of the company's sales capabilities in both the UK and Europe





# NEW LEADERSHIP

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# BOARD AND MANAGEMENT CHANGES COMPLETE

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## *CEO transition and Board renewal complete*

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Board and management will complete a thorough review of Palla's strategy and operations in Q4 2021

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Giles Moss commenced as CEO in September 2021, bringing over 30 years of commercial leadership and operations experience in the pharmaceutical industry. He will be based in the UK

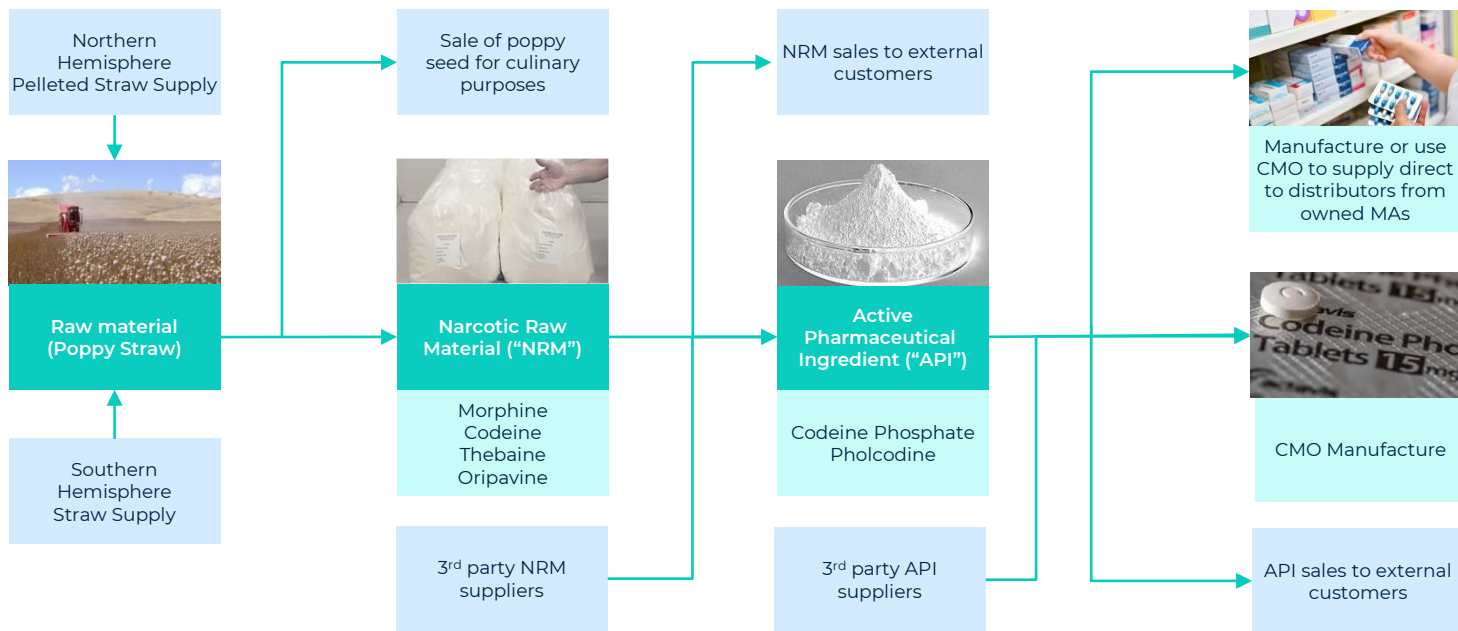
As Vice President and General Manager Europe at GW Pharmaceuticals, Giles was central to the successful ex-US launch of a new highly regulated orphan medicine for epilepsy. From 2016, Giles successfully built-out the core international functions and the commercial organisation across Europe

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# OPTIONALITY ACROSS THE SUPPLY CHAIN

*Supply chain from “farmgate to pharmacy”; MAs completes product offering*



# CRITICAL SUCCESS FACTORS AND LOOKING AHEAD

## *Meet production milestones, execute the sales strategy and explore options to drive capital flexibility*

Goal to exit the 2021 Year with a proven and scalable business model capable of generating positive free cashflow by:

- 1. Achieving Finished Dosage production run rates close to capacity.** Underpinned by a continued focus on manufacturing excellence initiatives in Norway which has included new maintenance planning and standards for key equipment ('reactive to predictive'), cross-skilling of API and warehouse staff in FD production, rigorous establishment of rated operating limits complemented by routine shift reporting and downtime PLAN-DO-CHECK-ACT improvement cycles
- 2. Execution of sales strategy.** Continued penetration of UK wholesaler market to gain further share of wallet
- 3. Review asset ownership versus sale and leaseback.** A process is being undertaken to investigate the sale and leaseback of the manufacturing facilities in Melbourne and in Norway. The combination of these initiatives will significantly add to capital flexibility going forward
- 4. Explore new opportunities.** Palla is a Pain company and there are opportunities to explore adjacent pain related markets, leveraging off current capabilities to hold narcotic licenses, process, manufacture and store controlled substances and move them around the world within highly regulated pharmaceutical markets



# OUTLOOK



# 2021 OUTLOOK

## *Revenue and earnings skewed to second half of 2021 as sales ramp up*

Foundations of the business model now in place with expectation of increasing sales volumes and of both internal and CMO FD production capacity being highly utilised exiting 2021

UK Manufacturing with CMO partnership providing additional capacity and optionality to derive maximum value from owned MAs, and along with 3PL logistics provider partnership, reduces product distribution complexity and delivery capability risks

Revenue and margins expected to increase through 2H21 as product sales increase and additional capacity is utilised, and further planning for earnings accretive capacity expansion takes place

Focus on cashflow generation, improved operating leverage with increased sales and production volumes and complete sale and lease back plans for manufacturing sites

Plans to explore broader capability, leveraging off manufacturing, shipping and regulatory expertise



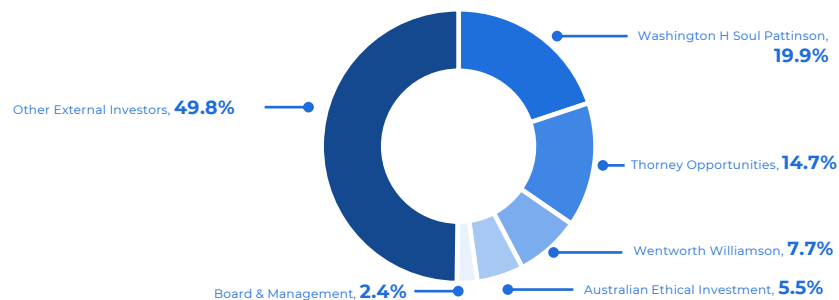


# APPENDICES



# CAPITAL STRUCTURE & SUBSTANTIAL SHAREHOLDERS

## SHAREHOLDERS



## CAPITAL STRUCTURE

Share Price (29 September 2021)	\$0.30
Fully Paid Ordinary Shares	125.9m
Market Capitalisation (29 September 2021)	\$48.6m
Net debt (30 June 2021)	\$14.1m

## DIRECTORS & SENIOR MANAGEMENT

Simon Moore	Non-Executive Chair
Stuart Black	Non-Executive Director
Sue MacLeman	Non-Executive Director
Iain Ross	Non-Executive Director
Giles Moss	Chief Executive Officer
Brendan Middleton	Chief Financial Officer



# NON-GAAP FINANCIAL MEASURE RECONCILIATION

## Reconciliation of Operating EBITDA (non-GAAP financial measure) to statutory Net Profit/(Loss)

A\$ ('000)	1H21	1H20
<b>Net Profit/(Loss) for period</b>	<b>(33,106)</b>	<b>(9,015)</b>
<i>Add:</i>		
(+) litigation settlement expenses	97	-
(+) Impairment of inventory to net realisable value	11,526	-
(+) Impairment of non-financial assets	8,225	-
(-/+ ) (gain)/loss from non-core equipment disposal	49	(9)
(+) depreciation and amortisation	1,234	1,355
(+) net finance expenses	933	999
<i>Less</i>		
(-) other income	(3)	(75)
<b>Operating EBITDA</b>	<b>(11,045)</b>	<b>(6,745)</b>

- The consolidated financial statements of the Group are general purpose financial statements which have been prepared in accordance with Australian Accounting Standards (AAS) adopted by the Australian Accounting Standards Board (AASB) and the Corporations Act 2001. The consolidated financial statements comply with International Financial Reporting Standards (IFRS) adopted by the International Accounting Standards Board (IASB)
- This presentation includes a non-GAAP financial measure which is not prepared in accordance with IFRS being:

**Operating EBITDA:** calculated by adding back (or deducting) finance expense/(income), income tax expense/(benefit), depreciation, amortisation, litigation settlement expenses, acquisition related expenses, transaction integration services, agricultural area trialling expenses, inventory impairments, goodwill and non-financial asset impairments, losses from discontinued operations, gains/losses on disposal of non-core plant and equipment, and deducting other income and depreciation expense from discontinued operations, to net profit/(loss) after tax

- The Group uses this measure internally and believes this non-GAAP financial measure provides useful information to readers to assist in the understanding of the Group's financial performance, financial position or returns, but that they should not be viewed in isolation, nor considered as a substitute for measures reported in accordance with IFRS
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