

PALLA PHARMA

# 2020 HALF YEAR RESULTS

31 August 2020

ASX: PAL

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## **AGENDA**

- Non-GAAP Financial Measure Reconciliation

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## PALLA PHARMA OVERVIEW

Fully integrated opiate manufacturer from farm gate to tablet production

Lowest cost producer of Narcotic Raw Material (NRM), the highest cost input for opiate based Active Pharmaceutical Ingredient (API) and Finished Dosage Formulation (FDF) products

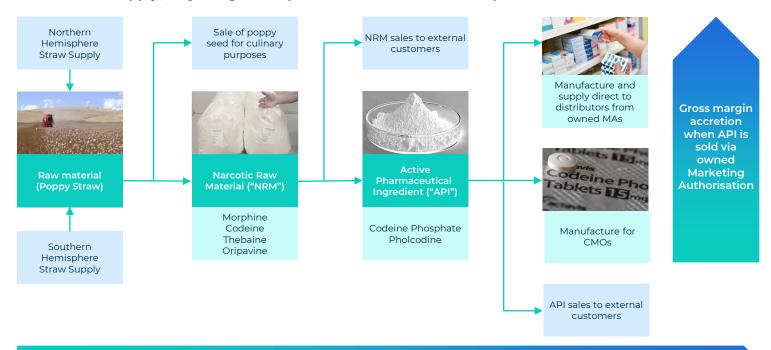
Manufacturer of opiate-based tablets for Contract Manufacturing Organisations (CMO) or direct to distributors from owned Marketing Authorisations (MAs)

Rapidly growing global supplier of opiate-based pain relief medicines with plans for high-value anti-addiction products



## **FULLY INTEGRATED GLOBAL SUPPLY CHAIN**

#### Diversified straw supply; fully integrated operations now with ownership of MAs



Accretive gross margin for the group as NRM converted to higher value products through the supply chain



## CAPTURING FURTHER VALUE FROM SUPPLY CHAIN

#### Ownership of finished dosage MAs underpins path to long term earnings growth

## ESTABLISH SUSTAINABLE MANUFACTURING FOOTPRINT

- Relocated factory to Victoria
- Invested in capacity for long term growth
- Listed on ASX

#### SECURE STRAW SUPPLY AND MARKET ACCESS

- Drove legalisation of NSW/VIC poppy cultivation
- Secured secondary straw supply from Europe
- Acquired Norway operations
- Developed tolling opportunity with prior industry competitors

## INTEGRATE NORWAY & ACCELERATE REVENUE GROWTH

- Demonstrated Market share growth in Codeine Phosphate (CPO) and Pholcodine API's, and opiate based FDF
- Expanded API manufacturing capacity to meet sales growth
- CMO division turnaround
- NRM volume growth as increased volumes drive down costs
- Secure additional Northern Hemisphere straw supply
- Cost reduction benefits from increased manufacturing efficiencies and scale
- Delivered 41 tonnes of opiate equivalent sales volumes

## ACQUIRE MAS TO DRIVE VOLUME AND VALUE

- Acquired 7 Marketing Authorisations to supply directly to distributors in UK
- Capturing greater margin through acquisition of Marketing Authorisations
- Exit legacy low-margin nonopiate CMO contract, freeing up capacity for higher margin MAs products
- Streamline production with leaner operation, driving operational leverage
- Validation of first MAs on track, targeting sales in Q4 2020

## FOUNDATION SET TO DELIVER SHAREHOLDER RETURNS

- # Strong Q4 2020 to build momentum for rapid sales growth in early 2021
- # Access to straw for near term growth secured
- # Continuing to establish a global diversified growing platform
- # API and tableting capacity requiring limited new capex
- # Planned expansion into new geographic markets-FDF MAsand anti-addiction

2015 to 2017

2018 / 2019

2020

2021 / 2022



## **NAVIGATING THROUGH COVID-19**

#### Victorian and Norwegian facilities continue to operate with limited impact from COVID-19

Pharmaceutical product manufacturing is considered a Permitted Industry and can continue to remain open for on-site work

In March 2020 Palla implemented strict COVID-19 safe operating procedures, including the provision of additional PPE, staggered shifts and breaks, and physical distancing requirements

Higher than normal inventory level maintained to mitigate risks from supply chain interruptions. Industry wide paracetamol shortages have impacted the pharmaceutical industry including the opiate sector

Inventory levels expected to decrease during 2H20 freeing up working capital while maintaining sufficient stock to minimise supply chain risk

Palla continues to remain in contact with the Victorian Government to ensure its supply of an essential product remains uninterrupted







## 1H20 RESULTS OVERVIEW

#### 1H20 was a transition period through which the company positioned itself for higher growth

Revenue impacted by early exit of non-opiate based supply agreement and lower API volumes due to major UK customer losing its manufacturing license; revenue expected to accelerate in 2H20 from sale of opiate based FDF products under owned MAs

Reduction in gross profit driven by reduced API volumes and lower seed sales (related to weather) reducing the size of the Australian harvest

Indirect overhead cost base reduced by ~20%, with effect from April 2020 following exit of the non-opiate CMO supply agreement

Operating EBITDA<sup>(a)</sup> impacted by the decline in revenue and gross margin, partly offset by indirect overhead cost reduction

Net debt increased with the acquisition of MAs and additional inventory to avoid COVID-19 supply disruption; existing debt facility is expected to provide sufficient headroom to support execution of current strategy and business plans.

Revenue (\$)

On 1H19 to \$12.3m; impacted by planned supply agreement exit.

-54.9%

Gross Profit (\$)

-81.9%

On 1H19 to A\$1.7m; uplift through 2H20 with MAs supply commencing

Indirect Overhead (\$)



-19.6%

On 1H19 to A\$7.4m; reset cost base post supply agreement exit

Operating EBITDA(a) (\$)



-\$7.0m

On 1H19 to -\$6.7m; impact of temporary margin decline

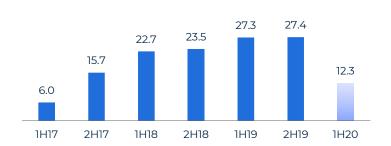
(a) Operating EBITDA is a non-GAAP financial measure – see appendix fo reconciliation of Operating EBITDA to statutory net profit/(loss) after tax.



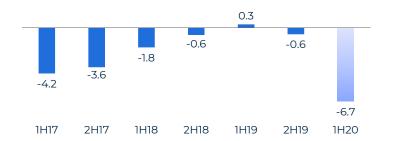
## HALF YEAR RESULTS TREND

#### Expect significantly accelerated growth in H2 onwards after short term rebasing of business

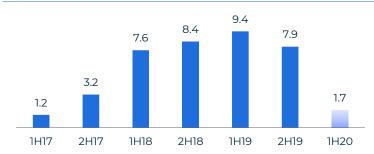
#### Revenue (\$M)



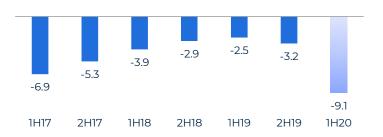
#### Operating EBITDA\* (\$M)



#### **Gross Profit (\$M)**



#### Underlying NPAT \* (\$M)

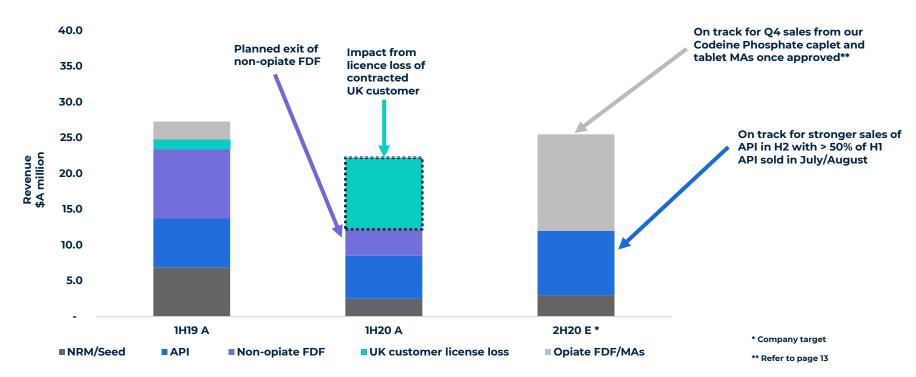


<sup>\*</sup> Operating EBITDA and Underlying NPAT are non-GAAP financial measures – see appendix for reconciliation of Operating EBITDA to statutory net profit/(loss) after tax



## **TRANSITIONING BUSINESS TO 2H 2020**

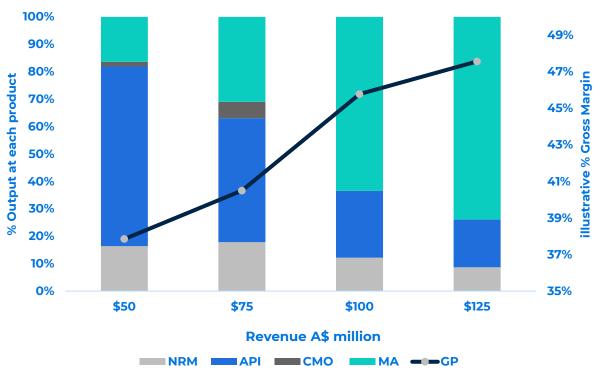
Exit from legacy non-opiate CMO supply agreement and transition into accelerated growth in H2 2020





## SIGNIFICANT EARNINGS UPLIFT FROM HIGHER MA OUTPUT

Transition from API to MA sales increases revenue by 2.4X/kg and significant GP uplift at current NRM capacity





## MARKETING AUTHORISATIONS

JARROD RITCHIE
CHIEF EXECUTIVE OFFICER



## MA APPROVALS ON TRACK

#### Stages 1-2 complete, Stage 3 to be completed by Q4 2020

#### Stage 1. Completed (NRM to API):

- 1. NRM Capacity circa 70tn in Australia
- 2. Expansion of Norway API Capacity to 70th completed
- 3. Shift from NRM sales to API sales sees customer base move from 5 to 55

#### Stage 2. Capability completed (API to CMO):

- 1. Capacity expanded with termination of non-opiate CMO contract
- 2. Reduced complexity and increased plant utilisation uptime
- 3. Reduced indirect overhead cost base; 1H20 down 20% compared to 1H19

#### Stage 3. On track - (API to MA):

- 1. 7 MAs acquired; 2 MAs have completed validation.
- 2. Next steps include stability trials and approval by the MHRA of Palla Norway as an approved manufacturing site
- 3. On track for first MA sales to commence in Q4 2020







## MA APPROVALS ARE A CRITICAL STRATEGIC MILESTONE

#### Significant uplift in margin and revenue when selling opiate in a MA

For every 1kg of Codeine Phosphate in our own MA we generate approx. A\$ 1,200/kg in revenue compared to approx. A\$ 500/kg when sold as an API.

Palla is currently completing documentation of 30/500mg Tablet and Caplet which target the most significant market opportunity.

First sales under Codeine Phosphate 30/500mg Tablet and Caplet to commence in Q4 2020, once approved.

Following the successful validation and MHRA approval for these two MAs, Palla will focus on validation and sales of its remaining 5 MAs and start to develop new MAs

The initial focus is on the UK market, with other European markets to follow, targeting France and Spain in FY21

#### Palla Pharma Owned MAs

- 1. 30/500mg Codeine Phosphate Caplet
- 2. 30/500mg Codeine Phosphate Tablet
- 3. 8/500mg Codeine Phosphate Tablet
- 4. 10/500mg Dihydrocodeine Tablet
- 5. 20/500mg Dihydrocodeine Tablet
- 6. 30/500mg Dihydrocodeine Tablet
- 7. 30mg Dihydrocodeine tablets



## **ELEVATED PRICING IN TARGET MARKET (UK)**

#### The UK market has two major suppliers currently unable to supply product leading to shortages

The sale price of a 100-tablet packet (Codeine/Paracetamol 30mg / 500mg) has increased significantly since O2 2018 from approx. £2.50 to over £4.00 per 100 pack\*

Palla receives 70-75% of the retail/hospital price as a MA holder selling to pharmacies and wholesalers

Utilising full packaging capacity at Norway, monthly revenue is expected to exceed \$A4 million based on O2 2018 pricing

Opportunity to increase monthly FDF revenue to \$A12m following a \$A 4 million capex on capacity expansion

Once approved by regulators, Palla expects earnings generated from Codeine Phosphate sold in tablet/caplet form under MAs to be a significant contributor moving forward at a significantly higher % GP



<sup>\*</sup>Based on IQVIA data from the UK pharmacy network and hospitals

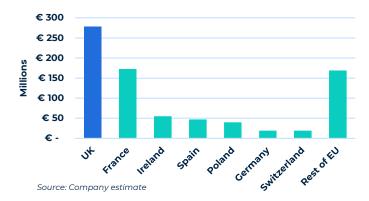
## **€802m EUROPEAN CODEINE PHOSPHATE MARKET**

#### Palla enters the UK, the largest European CPO related MA market; First sales to occur in Q4 2020

Palla owns 3 UK registered MAs for Codeine Phosphate combinations in both Caplet and Tablet form: 30/500mg Caplet, 30/500mg Tablet and 8/500mg Tablet

The acquired MAs enable access to the €278m UK market for codeine and dihydrocodeine tablet sales.

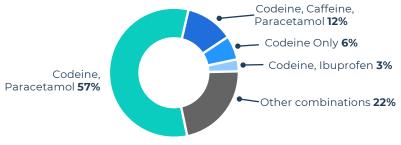
Targeting to enter other European markets using these MAs in FY21, including France and Spain



#### Palla now owns MAs for the most popular form of Codeine in EU

Codeine, Paracetamol accounts for 57% (€455m) of the EU market

Ongoing trials to enter the second biggest product group, Codeine, Caffeine and Paracetamol, accounting for 12% of EU market



Source: Company estimate



## APPROVAL OF MAS DRIVE SIGNIFICANT MARGIN GROWTH

#### Significant sales mix and gross margin uplift expected following first MA sales in Q4 2020

#### **Revenue mix:**

- 1. As previously communicated, FY20 Revenue expected to be a modest decrease on prior year with significant uplift in FY21-22 driven by increase in MA related sales
- 2. Product mix change in FY20 with the early termination of the non-opiate CMO contract and first MA related opiate product sales in 2H
- 3. FY20 Revenue and earnings heavily skewed to 2H20 with first MA related tablet sales to occur in Q4 2020

#### **Gross Profit mix:**

- 1. Despite modest decrease in FY20 revenue, Palla expects significant uplift in FY20 Gross Profit driven by high margin MA related sales in 2H20
- 2. Early exit from non-opiate CMO contract delivered significant indirect overhead cost savings effective from April 2020
- 3. Higher margin product mix change will see gross profit increase at a faster rate than revenue over FY21-22 period





## TRADING RESULT SUMMARY

#### Revenue impacted by planned exit from non-opiate CMO supply agreement and lower seed/API volumes

A\$ million	1H20	1H19	Change %
Revenue by Business Unit:			
NRM & Seed	2.5	6.9	<b>↓</b> 63.8%
API	6.0	8.2	<b>↓</b> 26.8%
Finished Dosage	3.8	12.2	<b>↓</b> 68.9%
Total Revenue	12.3	27.3	<b>↓</b> 54.9%
Gross profit	1.7	9.4	₹ 81.9%
Gross margin (%)	14.0%	34.6%	<b>4</b> 20.6%
Credit loss provision	1.0	-	<b>↑</b> nm
Indirect overhead	7.4	9.2	<b>1</b> 9.6%
Operating EBITDA <sup>(a)</sup>	(6.7)	0.3	<b>↓</b> nm
Significant items	(O.1)	1.7	<b>↑</b> nm
Reported EBITDA	(6.6)	(1.4)	<b>↓</b> nm

- Lower seed revenue due to reduced domestic crop (weather related) and shift to increased offshore straw supply
- API revenue down compared to 1H19, impacted by a major UK customer loss of manufacturing license
- Finished dosage revenue down compared to 1H19 due to the planned early termination of legacy non-opiate based CMO supply agreement
- Gross margin negatively impacted by timing of production inefficiencies associated with non-opiate based supply agreement termination and impact of reduced API volumes compared to 1H19
- Credit loss provision due to slow payment by major UK customer; proceedings commenced and expect to recover in full
- Indirect overheads reduced by ~20% from termination of non-opiate based finished dosage supply agreement



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

2020 Half Year Results

## TRADING RESULT SUMMARY (CONT'D)

#### Gross margin % impacted by termination of CMO supply agreement and reduced API and seed sales volumes

#### **Gross margin % negatively impacted during 1H20**

Production inefficiencies and headcount reduction delays associated with the early exit of the non-opiate CMO supply agreement

Major UK customer's operating licence was suspended in November 2019 for unexpectedly prolonged period, impacting planned volumes to be shipped through 1H20 and API production efficiency

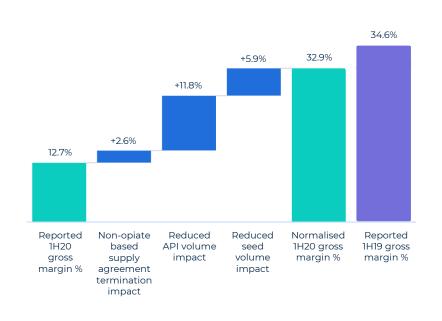
Lower seed sales volumes accounted for ~30% of the gross profit reduction compared to 1H19 and 5.9% of the variance in reported gross margin %

Adjusting for these impacts a "normalised" gross margin % of ~33% would have been realised

NRM and API production volumes across the business were lower leading to an increased unit cost of production which is not expected in future periods

Further margin improvement is expected through sales of higher margin opiate based MAs commencing 2H20

#### Estimated gross margin impact analysis (%)





## **INCOME STATEMENT SUMMARY**

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

A\$ million	1H20	1H19	Change \$
Reported EBITDA	(6.6)	(1.4)	(5.2)
Depreciation and amortisation	1.4	1.2	0.2
Reported EBIT	(8.0)	(2.6)	(5.4)
Underlying EBIT (before significant items shown below)	(8.1)	(0.9)	(7.2)
Net finance expenses	(1.0)	(1.5)	0.5
Income tax benefit	0.0	0.1	(O.1)
Net Profit/(Loss) (before significant items shown below)	(9.1)	(2.3)	(6.8)
Significant items	0.1	(1.7)	1.8
Reported Net Profit/(Loss)	(9.0)	(4.0)	(5.0)

- Underlying EBIT (EBIT before significant items) impacted by reduced gross profit contribution compared to 1H19
- Net finance expenses reduced by ~33%, or \$0.5m, compared to 1H19 due to reduced debt facility utilisation
- Reported Net Loss increased compared to the prior corresponding period due to reduced gross profit contribution; prior period significant items comprised primarily costs associated with high codeine patent litigation



## CAPITAL EMPLOYED SUMMARY

#### Net working capital reduction; increased net debt supporting Marketing Authorisation acquisitions

A\$ million	Jun 2020	Dec 2019	Change \$
Trade & other receivables	7.5	13.4	(5.9)
Contract assets	3.2	6.0	(2.8)
Inventories			
- Raw materials	8.1	8.6	(0.5)
- Work in progress	18.8	15.4	3.4
- Finished goods	2.5	0.4	2.1
Total inventories	29.4	24.4	5.0
Trade & other payables, provisions	(11.5)	(12.7)	(1.2)
Net working capital	28.6	31.1	(2.5)
Cash	1.6	2.0	(0.4)
Borrowings	12.8	5.5	7.3
Net debt	11.2	3.5	7.7
Contributed equity	211.0	211.0	-

- Trade & other receivables reduced due to lower sales revenue
- Contract assets reduced due to the termination of the non-opiate CMO contract where additional safety stock required to be held
- Raw materials and work in progress inventory increased to buffer against any COVID-19 supply chain interruptions; focus in 2H20 to reduce to normalised levels
- Net debt has increased to support the acquisition of Marketing Authorisations
- Standby debt facility is expected to provide sufficient headroom to support execution of current strategy and business plans





## STRATEGIC INITIATIVES

#### How Palla Pharma is delivering on its strategic objectives

#### Develop strong foundation for growth



- One of six licensed NRM producers globally; one of three fully integrated suppliers
- Lowest cost producer NRM globally; continue to develop and refine production processes (complete)
- Globally diversified poppy straw supply chain with dual hemisphere supply strategy (complete)
- Highly experienced management team (appointed FDF UK based Sales Director)

#### Penetrate existing markets



- Fully integrated supplier provides multiple channels to market (acquired MAs in FY20)
- Exploit lowest cost to produce competitive advantage and reliability of supply through diversified poppy straw sourcing strategy (complete)
- Secure long-term supply agreements (ongoing)
- Expect first sales into South America in H2 2020 (on going)

#### Continue to explore and develop new markets



- Significant unmet demand in developing countries with 92% of global supply consumed by 15% of the global population
- Strong population growth demographics in developing countries with lack of access to pain medication
- Activating existing and referral relationships with agents in Africa and Asia (continuing to develop – first sales into Africa and Asia in FY19)

#### **Development of new products**



- Develop suite of opiate based API's (FY20/21)
- Target anti-addiction API's (FY21)
- Obtain marketing authorisations to expand opiate based Finished Dosage capability (acquired MAs in FY20)
- Continue to explore market consolidation and downstream value-add acquisition opportunities (ongoing)



### **2020 OUTLOOK**

#### Revenue and earnings to be heavily skewed to 2H20

FY20 revenue and earnings expected to be heavily skewed to 2H20 with first MA related sales in Q4 2020

\$A4m monthly revenue opportunity for MA related sales at current capacity, with \$A12m monthly revenue opportunity following \$A4m capex on capacity expansion in 2021

MA validation on track, with 3 validation batches completed, meeting the required specifications; Commercial tablet supply to commence pending MHRA approval

Final approval by the MHRA of Palla Norway as an approved manufacturing site

Plans for FDF expansion and new product development remains a key focus for 2020

FY20 revenue is expected to see a modest decrease YoY with an uplift expected in FY21-22; significant gross profit uplift expected in FY20 driven by high margin MA related sales in 2H20

Continue to address inventory and working capital levels; expect raw materials and work in progress reduction through FY20 as high codeine poppy straw is converted and sold; reduce net debt



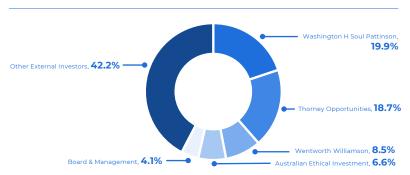






## **COMPANY OVERVIEW**





#### **CAPITAL STRUCTURE**

Share Price (28 August 2020)	\$0.90
Fully Paid Ordinary Shares	125.9m
Market Capitalisation (28 August 2020)	\$113.4m
Net debt (30 June 2020)	\$11.2m

#### **DIRECTORS & SENIOR MANAGEMENT**

Simon Moore	Independent	Non-Executive Chairman
Jarrod Ritchie		Chief Executive Officer
Stuart Black	Independent	Non-Executive Director
Todd Barlow		Non-Executive Director
Sue MacLeman	Independent	Non-Executive Director
Mark Licciardo		Company Secretary
Brendan Middleton		Chief Financial Officer



## NON-GAAP FINANCIAL MEASURE RECONCILIATION

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

A\$ million	1H20	1Н19
Net Profit/(Loss) for period	(9,015)	(4,084)
Add:		
(+) litigation settlement expenses	-	1,607
(+) acquisition related expenses	-	122
(-/+) (gain)/loss from non-core equipment disposal	(9)	-
(+) depreciation and amortisation	1,355	1,228
(+) net finance expenses	999	1,558
(+/-) income tax expense/(benefit)	-	(84)
Less		
(-) other income	(75)	(76)
Operating EBITDA	(6,745)	271

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- 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, gains/losses on disposal of noncore plant and equipment, and deducting other income, to net profit/(loss) after tax.
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