



PALLA PHARMA

ASX ANNOUNCEMENT

Monday 31 August 2020

Half Year Results Announcement and Investor Conference Call

- **1H20 WAS A TRANSITION PERIOD THROUGH WHICH THE COMPANY POSITIONED ITSELF FOR HIGHER GROWTH**
- **EXPECT SIGNIFICANTLY ACCELERATED GROWTH IN 2H20 ONWARDS AFTER SHORT TERM REBASING OF BUSINESS**
- **GROSS PROFIT UPLIFT EXPECTED FOLLOWING FIRST MARKETING AUTHORISATION PRODUCT SALES IN Q4 2020**
- **PLANNED NON-OPIATE CMO EXIT AND MAJOR CUSTOMER LOSS OF LICENCE LARGEST IMPACT ON 1H20 RESULTS**
- **JULY/AUGUST 2020 API SALES 50% of 1H20 VOLUME**

Palla Pharma Limited (ASX:PAL), a fully integrated opiate manufacturer and supplier to the global pain relief market, announced its results for the half year ended 30 June 2020 (1H20), which saw the company make strong progress in transitioning from supplying lower-margin non-opiate products to higher-margin opiate-based products via the recently acquired Marketing Authorisations (MAs).

1H20 Result overview (vs 1H19)

- 1H20 Revenue down to \$12.3 million (1H19 \$27.3 million)
- Gross Profit down to \$1.7 million (1H19 \$9.4 million)
- Operating EBITDA loss of \$(6.7) million (1H19 \$0.3 million)
- Underlying NPAT loss of \$(9.1) million (1H19 loss of \$(2.3) million)

Commenting on the result, Managing Director and CEO, Jarrod Ritchie said, “As we previously communicated to the market, this year’s sales and earnings will be heavily skewed to 2H20 as we transition from a producer of lower-margin non-opiate products to higher-margin opiate-based products sold via Palla owned Marketing Authorisations (MAs) acquired during 1H20. Profitability in 2H20 will also be favourably impacted by the continued reduction in indirect overhead costs from the early exit of the legacy non-opiate supply agreement.

“Regulatory validation and the transfer of the MAs manufacturing license to our Norway facility is going very well. We expect strong sales of higher-margin opiate-based tablet and caplets to commence in the final quarter of 2020.

“As advised at the AGM, while 1H20 revenue was expected to be lower, FY20 revenue will be modestly lower to flat year on year (YOY) with a significant uplift expected in revenue and gross profit through FY21 and FY22, driven by MA sales, once approved and higher API sales. Further, in the near term we expect a significant gross profit uplift in FY20 driven by high margin MA related sales in Q4 2020.”

Result overview

The 1H20 revenue decline to \$12.3 million was impacted by the planned early exit from a non-opiate based supply agreement, lower poppy seed sales volumes due to reduced (weather related) domestic poppy straw growing area, and lower API volumes due to a major UK

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customer losing its manufacturing license which had committed contracted volumes to the company.

Gross Profit of \$1.7 million was impacted by timing of the planned early exit from the legacy non-opiate based supply agreement, reduced poppy seed margin contribution due to a reduction in domestic growing area, increased focus on offshore poppy straw supply, and significantly lower Active Pharmaceutical Ingredients (API) volumes due to the prolonged manufacturing license suspension of a major API customer. With the non-opiate based supply agreement ended, the indirect overhead cost base was able to be reduced by approximately 20 percent for the half, resetting the cost base ahead of the higher-margin MA sales commencing in Q4 2020.

The Operating EBITDA loss of \$(6.7) million was impacted by the decline in revenue and gross margin, partly offset by indirect overhead cost reduction.

The company continues to strengthen its foundation for the future as it continues to focus on completing its strategic shift to downstream, margin accretive FDF supply. Regulatory approval is nearly complete for two of the seven acquired MAs. The company is well positioned to benefit from the operational leverage with higher margin MA sales to start in Q4, supported by reduced manufacturing complexity and increased plant utilisation, reduced headcount and a lower cost base due to the early exit from legacy lower margin non-opiate based supply agreement.

Imminent supply of Palla generic FDF (using our own MAs) finally enables PAL to combine the cost effectiveness of NRM Supply from Victoria (Australia), the ability to convert to API and FDF in Norway, which will further enable access to new markets providing a future earnings growth engine for the business.

Continued operations at Victoria and Norway facilities

The company's Melbourne and Norway facilities continued to operate under various 'Permitted Industry' exemptions as manufacturers of pharmaceutical product. In March 2020, the company implemented strict COVID-19 safe operating procedures at both facilities, including the provision of additional PPE, staggering shifts and breaks, and adherence to physical distancing requirements in shared working areas. To date this has proved effective in keeping the workforce safe.

While we have seen both positives and negative effects from COVID-19, in specific areas there has been an overall business disruption with regard to shipping costs, efficiency of interactions with customers, slowness in receivables and in some country specific examples (Italy) an inability to obtain co-excipients such as paracetamol which has delayed H1 API orders into H2 2020.

Demand however remains strong as Codeine based products have been included in the UK governments list of essential medicines with increased prices being observed in the UK market.

1. All codeine products have since the start of the year been on the list of products that cannot be hoarded or parallel exported.
 - a. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/892354/Medicines_that_cannot_be_parallel_exported_from_the_UK_15_June_2020.csv/preview

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2. Co-Codamol 30/500mg is on (from 31 March 2020) list of urgent COVID19 products – and there is a limit on the number that can be supplied
 - a. <https://psnc.org.uk/our-news/covid-19-urgent-supplies-ofcontrolled-drugs/>

The company continues to hold higher than normal inventory levels across all aspects of the business to mitigate supply line interruptions during the pandemic. Elevated inventory levels are expected to decrease over the next six months, freeing up working capital.

Validation batches passed, stability trials started for first MA in Norway, targeting sales in Q4 2020

Palla Pharma Norway is well progressed with the validation of the acquired 30/500 Co-Codamol product MAs. All three validation batches have been completed with analysis of the validation batches for both the tablets and caplets, meeting the required specifications.

Co-Codamol 30/500mg Tablets and Caplets have been packed and have commenced stability trials.

Next steps that will enable sales in Q4 2020 are:

1. Satisfactory stability trials and submission of Data to the Medicines and Healthcare Regulatory Agency (MHRA)
2. Approval by the MHRA of Palla Norway as an approved manufacturing site.

Pricing continues to increase in the UK market for opiate-based products due to supplier shortages

The price of Codeine/Paracetamol 30mg / 500mg has increased significantly since Q2 2018 – from £2.50 to over £4.00 per 100 pack according to the IQVIA data from the UK pharmacy network and hospitals.

Utilising its full packaging capacity at Norway facility the revenue generated per month is expected to exceed approximately A\$4 million at original pricing levels. Palla plans to expand capacity in 1H 2021 to allow for additional demand, resulting in expected total revenue per month of approximately A\$12 million after capital expenditure of approximately A\$4 million.

Multi-year opiate based FDF CMO contract extension

During the half-year period a multi-year opiate based Finished Dosage Formulation (FDF) CMO contract was extended to supply 270 million Codeine Phosphate tablets to a major UK customer. The contract extension equates to a minimum of eight tonnes of Codeine Phosphate equivalent and represents approximately four months packaging capacity.

Diversifying NRM raw material sourcing and ensuring uniformity in poppy straw quality

Australia had reduced growing area last season due to adverse weather events in NSW and a heightened focus on diversification of straw supply to offshore supply sources. The company continues to increase poppy straw sourcing from Northern Hemisphere sources and continues to focus on improving local expertise with increased farmer and aggregator engagement through the company's on-the-ground agricultural expertise in Europe.

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Debt recovery legal proceedings commenced seeking payment of outstanding invoices from major UK customer

The company has filed a claim in the High Court of Justice Business and Property Courts of England and Wales. The company is confident in its claim as all product supplied was ordered and delivered as per product specifications and expects to recover the amount owing in full. Despite this, a trade receivables impairment loss charge of \$1.0 million was recognised during the period.

Strategy update and Outlook

As previously communicated, the company expects a significant revenue and earnings skew to 2H20 as first MA sales start in Q4 2020.

The company is well positioned to rapidly grow revenue and earnings in 2H20:

- MA validation is on track, with three validation batches completed, meeting the required specifications
- MA sales start after certification of Palla Norway as an approved manufacturing site by MHRA
- At full capacity, ~A\$4 million monthly revenue opportunity exists for MA sales at early 2018 tablet/caplet prices.
- Manufacturing can commence (without sales) to build inventory prior to approval
- Elevated prices for Codeine/Paracetamol 30mg/500mg tablets/caplets due to supply shortages provide further margin upside. At least two of the four major customers have supply issues into the UK market at present meaning Palla will not have to lower prices to enter the market.
- A\$12 million monthly revenue opportunity following \$4 million capex spend
- FY20 revenue is expected to be modestly lower to flat YoY with a significant uplift expected in FY21-22
- Gross profit uplift expected in FY20 driven by high-margin MA-related sales in 2H20
- Continue targeted improvement in working capital and reduction of net debt.



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Conference call details

To pre-register for this conference and avoid a queue when calling, please use the following link below:

<https://sl.c-conf.com/diamondpass/10009518-invite.html>

You will be given a unique pin number to enter when you call which will bypass the operator and give you immediate access to the event.

If you are unable to register, then at the time of the conference you can call one of the numbers below and provide the **conference ID 10009518** to an operator:

- Attendee Dial-in (Australia Toll Free): **1800 455 963**
- Alternate Australia Toll Free: **1800 908 299**

This announcement has been authorised for release by the Board of Directors.

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About Palla Pharma Limited:

Palla Pharma Limited (ASX:PAL) is a vertically integrated opiate manufacturer from poppy straw growing through to tableting production. Palla Pharma has developed an innovative, efficient, and environmentally sustainable opiate manufacturing process based on a unique water-based extraction technology. The company is one of six licensed opiate producers globally, and one of three fully integrated suppliers from opiate extraction through to tableting production delivering on its strategy to secure access to regulated downstream narcotics markets by leveraging its production cost advantage.

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