



PALLA PHARMA

ASX ANNOUNCEMENT

Monday 10 February 2020

Palla Pharma Limited Investor Update

Due to recent share price fluctuations, industry related media commentary and the rapidly changing nature of the global pain relief market, Palla Pharma Limited (ASX:PAL) provides this update prior to the release of its full year financial results on 27 February 2020.

Overview:

1. The recent short-term share price drop was dominated by a single shareholder selling a significant block of shares over a short period. The share price has rebounded 10.86% in the last 2 days of trading.
2. After a protracted period of negotiation, PAL has entered into an option agreement to acquire its largest UK customer, a manufacturer of finished dosage Codeine Phosphate.
3. In conjunction with the option, PAL acquired four Marketing Authorisation's (MA's) from the UK customer for supply of Codeine based products into the UK. These MAs will allow PAL to supply meaningfully margin accretive Codeine and Dihydrocodeine based tablets (generic and branded) into the UK from Norway in 2H 2020.
4. The 2019 total revenue expectation will be reduced due to a French based NRM customer requesting that the supply of product expected in Q4 2019 be delayed and operating issues at two UK based customers in the same period which reduced their product demand.
5. On 5 February 2020, PAL received regulatory approval (CEP) to manufacture Codeine Phosphate from Morphine NRM in the UK at a CMO site, significantly increasing our API supply capability without further investment.
6. Recent media regarding increased monitoring of opiate pain relief in Australia is not expected to impact PAL business. Opiates remain an essential medicine as referenced by the World Health Organisation (WHO) and we see strong demand for product from existing and prospective customers.

1. Recent Share Price Trading

The recent share trading was dominated by the sale of significant share block by a single shareholder over a short period. The number of shares involved constituted many weeks of average daily trading volumes. PAL understands the seller has now completed the intended sell-down of its position. The share price shows signs of rebounding with an 8.02% improvement on Thursday 6 February and a further 2.86% on Friday 7 February trading.

2. UK Market Activities

a. Potential Acquisition of PAL's Largest UK Customer

Since July 2019, PAL has been in discussions with our major UK customer regarding the potential acquisition of their UK operations as part of PAL's strategy to continue to move down the value chain. The UK customer's manufacturing site has the capacity to tablet over 120 tonnes of Codeine Phosphate, which equates to revenue of approximately USD\$120m. This compares to TPI Norway's tableting capacity of 25 tonnes. In 2019 the UK based customer had revenue of £15m.

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PALLA PHARMA

Acquisition discussions have intensified since the last week of December, after the UK regulator imposed a three-month suspension of the target's operating licence. This suspension resulted in a need by the target for working capital and management support in the form of quality expertise. PAL agreed to provide the support, while conducting appropriate due diligence for the potential acquisition. To help address the target's working capital needs, PAL acquired four of the target's marketing authorisations, which will enable PAL to supply finished dosage formulation into the UK from its Norwegian facility starting in 2H 2020. In return for its management assistance and the investment of resources in the due diligence process, PAL has also been given an option to acquire the business at an attractive valuation. Should the acquisition be completed, PAL is highly confident it will not need to raise additional capital. The option expires at the end of March 2020.

b. Marketing Authorisations

PAL has acquired the following marketing authorisations for supply of Codeine based tablets into the UK.

- i. 30mg CPO/500mg Paracetamol Caplets
- ii. 30mg CPO/500mg Paracetamol Tablets
- iii. 30mg Dihydrocodeine/500mg Paracetamol Tablets
- iv. 10mg Dihydrocodeine/500mg Paracetamol Tablets

It is expected that the transfer of the MAs to TPI Norway will take approximately 6 months, allowing supply into the UK by August 2020. These marketing authorisations are highly margin accretive; enabling PAL to supply codeine and dihydrocodeine based tablets directly to UK pharmacies and wholesale distributors, and in the process capturing margin at every supply channel in the market.

3. Update on 2019 Financial Results

The Company completed its financial year on 31 December 2019 and, while the results are yet to be finalised and audited, it is likely that the full year result will see revenue towards the lower end of the analyst consensus range of \$53-60M and below the \$60m guidance from the last capital raising. We expect at this stage a small (c.A\$0.3m) full year reported EBITDA loss, rather than the previously expected EBITDA profit.

The revenue shortfall is due to a French based NRM customer delaying orders that were expected in Q4 2019, the temporary reduction of product demand at two UK based customers in the same period due to their internal operating issues and the 2019 Karo pricing adjustment due to the early termination of the CMO contract. The lower Q4 sales impacted EBITDA, inventories and cash.

The full year EBITDA result, that will be reported when finalised, was also impacted by a number of onetime expenses related to company operational improvement initiatives (quality control in Norway), regulatory compliance (legal expenses, EU serialisation related disruption), and research & development expenses (related to improving WIP recovery and new product development). If we were able to adjust for these onetime operational items, which are included in the reported EBITDA, then the Company would have reported a modest EBITDA profit result despite the sales shortfall discussed above. This outcome would have been considered a pleasing result by the Board.

4. CEP Approval

In January 2019, PAL submitted a "sister site" application for the conversion of Morphine to Codeine phosphate in a UK Manufacturing CMO. On 5 February 2020, PAL received confirmation from the European Directorate of Quality Medicines (EDQM) that the



PALLA PHARMA

application (CEP) had been approved. This outcome provides PAL with the following significant supply benefits:

- a. Supply of Morphine NRM directly to the UK, removing the need for API import quota which would otherwise have restricted supply to our UK customers
- b. Backup manufacturing capacity should Norway experience unexpected downtime

5. Recent Media

On Tuesday 4 February and Thursday 6 February, The Age and Sydney Morning Herald published articles titled "[Australia's Opioid Crisis](#)" and "[Opioid Crisis](#)" respectively. The articles make reference to the increased need for government regulation of the supply of opiate based pain medicines. PAL does not dispute the content of the articles; however, PAL considers that the need for increased regulation of the industry should be considered in the context of the fact that opiate based medicines are essential for the management of acute pain. Both articles conceded that there is a bona fide need for opiates medicines. The World Health Organisation (WHO) 2019 report "[List of Essential Medicines](#)" lists Codeine and Morphine as the essential medicine for Pain Relief and Palliative Care. PAL welcomes increased regulation to avoid abuse, while ensuring this essential medicine is available to all those in need.

6. Senior Executive Search

As previously highlighted at the time of the recent capital raising, PAL is looking to add a Group Executive to its management team. PAL engaged an executive recruitment firm in November to conduct a comprehensive search which is now well advanced. A further update will be provided at the time of the annual results release.

The Company will release its Full Year Results announcement on Thursday 27 February 2020 and will provide updates before then if material information arises.

This announcement has been authorised for release by the Board.

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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 novel 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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