PALLA PHARMA

ASX ANNOUNCEMENT

Monday 1 February 2021

Market Update - UK Marketing Authorisations, Current Trading & Business Review

- Core manufacturing site change MHRA approval granted but sales delayed while awaiting final MHRA approval of product leaflet variation
- Delays in the receipt of final MHRA approval is extending period of operating losses and rate of cash burn
- Board Review of strategy and operations commenced after departure of CEO

UK Marketing Authorisations

Further to the ASX announcement of 3 December 2020, Palla Pharma Limited (ASX:PAL) ("the Company"), a fully integrated opiate manufacturer and supplier to the global pain relief market, today announces that its applications to change the site of manufacture for its Co-Codamol tablet and caplet Marketing Authorisations to its Norway production facility have been granted by the UK medicines regulator (MHRA).

Whilst the site of manufacture change has been approved, and the MHRA assessor has approved the updated text of the Patient Information Leaflets that accompany the products, formal approval of the Marketing Authorisation holder and site of manufacture name change variations to the leaflet has not yet been granted. Neither the MHRA or the Company's regulatory advisers have been able to provide a precise timeline for this final review and approval to be completed. The Company has been informed that Brexit and COVID-19 have placed resourcing pressures on the MHRA which has extended timelines across all their activities. Production of tablets in bulk form will start immediately in anticipation of receiving approval; however, the packaging will be delayed until the variation is approved to alleviate the risk of repacking the tablets if a further change to the leaflets is needed.

The approved Co-Codamol products are a 30 mg Codeine Phosphate / 500g Paracetamol tablet and caplet combination, with the UK being the largest market in Europe for these products. The Gross Margin attributable to each kilogram of Codeine Phosphate sold as part of the approved Co-Codamol products is expected to be significantly higher than when sold in Active Pharmaceutical Ingredient (API) form or tableted form as a Contract Manufacturer.

The process for supplying the Company's Co-Codamol products requires that intending purchasers be qualified as customers to meet quality and regulatory requirements. Several prospective customers have been qualified, with a further pipeline of indicative customer interest established in anticipation of the products shortly becoming available for sale. Market conditions remain attractive with continued product shortages in the UK.

The Company has prioritised the manufacturing site change approval of the Co-Codamol products to target the UK's most significant market opportunity. Further submissions to the MHRA will be completed throughout 2021 for the remaining Marketing Authorisations acquired in 2020.

Current Trading Position

The delay of the receipt of the final approvals from the MHRA to start the production and sale of Co-Codamol products under the Company's marketing authorisations into the UK has caused the Company to generate greater than exected operating losses in the final quarter of 2020 and these losses have continued into the 2021 Year. At present, the business is using

Palla Pharma Limited
PO Box 2139 Melbourne, VIC 3001, Australia
T +61 3 9301 0800 / **F** +61 3 9301 0899 / **W** pallapharma.com / **E** info@pallapharma.com

approximately $1-2m of cash per month although this number will fluctuate with variations in API and Contract Manufactured Finished Dosage sales, and domestic poppy straw harvest commitments.

Board Review

Following the departure of the CEO late last year, the Board commenced a thorough review of the Company's strategy and operations. Paticularly close scrutiny is being given to the Company's various commercial opportunities and the current status of the Marketing Authorisation approval process for the UK and other European jurisdictions. While the Review is still ongoing, the Board remains confident that the Company will receive all the necessary regulatory approvals to progress the Marketing Authorisations to commercialisation and plans are well advanced for commercialisation.

However, due to factors outside the Company's control such as regulatory approval processes, logistical disruptions associated with the Brexit implementation and the ongoing effects of COVID-19, the Company cannot guarantee the timely receipt of the necessary approvals and, as a result, the Board is taking immediate steps to generate cash flow through the realisation of inventories, reduce cash outgoings through the implementation of various cost savings initiatives and exploring other options to reduce the potential financial risk to the Company posed by further delays. The Board will provide a further update as its review progresses.

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

For more information please contact:

Simon Moore
Chairman
Palla Pharma Limited
+61 3 9301 0800

Brendan Middleton
Interim CEO
Palla Pharma Limited
+61 3 9301 0800

Adrian Mulcahy
Investor Relations
Market Eye
+61 438 630 422
ir@pallapharma.com

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.