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Market release

17th February 2017

Market update

AFT Pharmaceuticals (AFT) has received confirmation that the United States Food and Drug Administration (FDA) will accept filing of its New Drug Application for *Maxigesic* tablets.

Additionally, AFT has received approval for a multi-million dollar fee waiver from the FDA by virtue of this first US filing being from a small entity. Under FDA rules a “small organisation” is defined as having less than 500 staff.

“We’re really pleased to complete the significant pre-filing requirements and also to gain approval for the fee waiver,” says CEO Dr Hartley Atkinson. “The waiver itself is significant and will save us approximately US\$2.4M (around NZ\$3.3M). Clearly now the work will shift to finalising the approval. Our development and regulatory teams have geared up for this important next step in getting *Maxigesic* into the US market.”

Although AFT has been licensed in 111 countries around the world, the next leg is North America comprising the US, Canada and Mexico. “North America is an important market and accounts for around 37% of the global target pain market for *Maxigesic*,” said Dr Atkinson. “Negotiations on licensing agreements for certain *Maxigesic* products have started for both the US and Mexico.”

AFT has already licensed *Maxigesic* to Swiss-based pharma, Acino AG, in Central America and the Caribbean. AFT also plans to file through Acino next month in these countries: Belize, Costa Rica, Dominican Republic, Haiti, El Salvador, Guatemala, Honduras, Nicaragua, Panama and Trinidad & Tobago.

On the local New Zealand market front, AFT was pleased to finalise termination and settlement of its current sole supply *Metoprolol* contract with the government drug funding agency, PHARMAC. During the earlier supply shortage period, AFT purchased additional *Metoprolol* from other suppliers to help maintain continuity of supply for patients across New Zealand. A final payment of NZ\$900,000 will be paid in the next financial year FY2018 to PHARMAC.

“Our ongoing relationship with Pharmac is important for our New Zealand based side of the business so it’s good to have this settlement completed,” said Dr Atkinson.

The company expects to meet the analyst consensus revenue projections of around \$70m for FY2017. On this basis, it has exercised its option under the CRG term loan to amend the revenue covenant to \$67.5m for FY2017.

[End of Release]

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