



Working to improve your health

Market release
29 September 2017

Market update

Clinical trials and development

AFT Pharmaceuticals (AFT) is pleased to announce that the pivotal clinical study for the intravenous (IV) *Maxigesic* formulation has now been closed. It is anticipated that the results will be available by the end of October. “This is a major part of our clinical trial program and the most expensive study we have conducted to date,” says Dr Atkinson.

Development of other key innovative products is proceeding well. Other studies completed recently include the *Maxigesic* oral liquid study, and the *Maxiclear* study with results expected to be available by the end of this calendar year.

Some further development work is still underway on the previously announced new *Maxigesic* formulations, *Maxigesic* dry powder stick and a faster acting version of *Maxigesic*. However it is not expected that significant clinical trial expenditure will be required for these new formulations.

AFT has also recently completed the first regulatory development meeting with the FDA in the United States for the first indication of its drug delivery and sinus treatment medical device, *NasoSURF*.

“This milestone is an important step in the development pathway for this project,” says Dr Atkinson. “This comes on top of the recent completion of Human Factor Studies conducted in the US, and successful completion of the Engineering Scale Production run at our contract manufacturing plant.”

Australian codeine update

Sales activities in Australia are well underway in preparation for the upcoming codeine rescheduling.

The rescheduling formally takes effect on 1 February 2018, meaning that codeine based painkillers will no longer be available over-the-counter, but will instead require a doctor's prescription.

"This change has seen a great deal of industry activity in the last few months. Our field force have been focused on *Maxigesic* in the build-up to the codeine rescheduling decision which takes effect this summer," says Dr Atkinson "We're also building up our product stock levels accordingly."

International Business Director

On the staffing front, AFT is pleased to announce the appointment of Ms Louise Clayton as its new Director of International Business. She will be based in AFT's main headquarters in Auckland and starts in November.

"Louise is a really good fit for us because of her background in international business, together with her previous experience in over-the-counter pharmaceuticals and branded products," says Dr Atkinson.

"On top of that she has a lot of experience in growing new business in multiple geographies in a public company setting, which we believe will add value to our organisation."

Dr Atkinson also notes that the timing of the appointment works well for AFT given the company's current high growth phase.

"Louise is coming on board at a time when we're focussing on driving the increase in *Maxigesic* revenues through both sales growth in existing markets, and in upcoming launches in over 100 new markets over the next 3 years."

Funding

Under its existing loan facility (April 2014) with Capital Royalty Group (CRG), AFT drew down US\$15m of the US\$30m full facility. The ability to make additional draw-downs expired in October 2016.

AFT and CRG have agreed to a new loan facility of up to US\$10m, US\$5m of which is a mandatory drawdown prior to 31 March 2018. It was also agreed that the repayments for all facilities will not be required to be made before maturity on 31 March 2020.

"This additional flexibility to the long-term debt facility removes any uncertainty around our short-term cash flows as we complete our clinical trial program, take advantage of the codeine rescheduling decision in our key Australian market, rollout *Maxigesic* launches in multiple international territories, and secure further licensing agreements and associated upfront income," says Dr Atkinson.

Summary of the new loan:

- US\$10m is available to drawdown, with a US\$5m mandatory drawdown prior to 31 March 2018.
- Repayments will not be required to be made before maturity on 31 March 2020. The terms of the existing facilities provided by CRG (entered into before AFT was listed) is amended to provide the option that no repayments are required before that date.
- Interest and fees for the new loan are the same as for the existing facilities provided by CRG.
- In the event that the new loan is repaid early it requires a total repayment of no less than 1.31 x principal, comprising principal, interest and fees.

Outlook

Trading is proceeding in line with analyst expectations, with a return to break even targeted in late FY2018 or FY2019. Further details will be provided with our interim results announcement in November.

[End of release]

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