Market Release
November 23 2017

FINANCIAL RESULTS FOR HALF YEAR ENDED 30 SEPTEMBER 2017

AFT Pharmaceuticals Limited (NZX; AFT, ASX; AFP) today announced its half-year unaudited financial results for the period ended 30 September 2017 (**H1FY18**).

Performance Highlights

- **Operating Revenues** of $36.6m for the first half of FY2018 to 30 September 2017 (H1FY18) were up 23% over the previous corresponding six month period (PCP) ended 30 September 2016 (H1FY17).
- **Operating Loss** of $6.7m (PCP $8.4m) has reduced with the growth in Operating Revenues and an improved Gross profit margin partially offset by the increased investment in Research and Development.
- ***Maxigesic*** is now being sold in ten countries – Australia, Brunei, Israel, Italy, Malta, New Zealand, Serbia, Singapore, United Kingdom and United Arab Emirates. Further country launches are in progress.
- ***Maxigesic*** is licensed in 124 countries, up from 110 in FY2017.
- **Product clinical studies** on track with 10 being conducted in FY2018.
- ***Nasosurf*** development is on track with Class I Medical Device completed in the key US market and the Class II FDA development pathway now confirmed. Pilot production batches are about to commence.
- **Research and Development** investment in our key global products has increased to $5.6m[1] for the six months (PCP $4.5m) and represents 15% of Operating Revenue (PCP 15%). We have successfully concluded our largest clinical trial, the Phase 3 for the intravenous (IV) form of *Maxigesic.* The completion of this study along with the *Maxigesic* Oral Liquid study represents a significant amount of our clinical trial expenditure planned at IPO.
- **Cash available** at 30 September 2017 of $7.2m following investment in Research and Development. In addition we have a US$10m facility available with the CRG Group.

[1] Total research and development includes the equity accounting for the joint venture

Financial Overview

Unaudited Group Operating Results NZ$'000	Six Month Period Ended September 30 FY2018	FY2017	Change ($)	Change (%)
Revenue	**36,561**	**29,787**	**+6,774**	**+23**
Cost of Sales	(22,256)	(19,018)	+3,238	+17
Gross Profit	**14,305**	**10,769**	**+3,536**	**+33**
Other Income	1,014	1,007	+7	+1
Selling and distribution expenses	(12,771)	(12,575)	+196	+2
General and administrative expenses	(3,618)	(3,135)	+483	+15
Research and development expenses	(4,982)	(4,276)	+706	+17
Equity Accounted Loss of joint venture entity	(616)	(210)	+406	+193
Underlying Operating Loss	**(6,668)**	**(8,420)**	**-1,752**	**-21**

Operating Revenue

Operating Revenue grew 23% to $36.6m for the six month period ended 30 September 2017 (PCP $29.8m) due primarily to the continued growth in our primary Australian market and the emerging Rest of World market.

- **Australia Revenue** grew by 38% to $20.2m (PCP $14.6m) and this market now makes up 55% of Group Operating Revenue. Strong growth in its main over-the-counter channel, with all products now available following the previous supply issues. *Maxigesic* continues to grow as the market prepares for the re-scheduling of codeine-based painkillers from over-the-counter to prescription only from 1 February 2018 (*Maxigesic* is codeine-free and is therefore exempt and remains available over-the-counter). It is apparent that the shift away from codeine is accelerating as the rescheduling date approaches. The speed of this shift and the relative market share gained by *Maxigesic* will contribute to the second half FY18 and onwards. The Hospital channel also had strong growth with successes in all of the significant state and private tenders.
- **New Zealand Revenue** grew by 5% to $14.1m (PCP $13.5m) and represents 39% of the Group Operating Revenue. Good growth in the over the counter market, which included the launch of *Crystawash* and *Crystasoothe* as extensions to the market leading *Crystaderm*. The Hospital channel also experienced good growth with the addition of several new products. Prescription declined as we finish the transition away from the low margin *Metoprolol* tender.
- **Rest of World Revenue** grew by 38% to $1.6m (PCP $1.2m) and now represents 4% of Group Operating Revenue. *Maxigesic* sales were made to Italy, United Arab Emirates and United Kingdom together with sales to Israel for the launch in that market. Additional small markets have been added such as Malta and Brunei.
- **Southeast Asia Revenue** grew by 14% to $0.6m (PCP $0.5m) and represents 2% of the Group Operating Revenue. The main market continues to be Singapore with over-the-counter growth.

Gross Margin

Gross Profit grew 33% to $14.3m (PCP $10.8m) driven by the operating revenue growth primarily in Australia and supported by growth in Rest of World and New Zealand.

The Gross Profit Margin improved to 39% (PCP 36%), driven by the growth of the higher margin over-the-counter products particularly in Australia and Rest of World. New Zealand also contributed with the growth in over-the-counter products at higher margins and the reduction in Prescription revenues at lower margins.

We expect the Gross Profit Margin to continue to improve as the strategy to increase the sales of over-the-counter products particularly in Australia and Rest of World markets continue to grow.

The NZ$ has been relatively stable on average over both the period's against our primary purchasing currencies of US$ at around 71.0 to 71.5 cents and Euro at around 62.0 to 62.5 cents and therefore has not significantly influenced margins in Australia, New Zealand or Southeast Asia. Rest of World sales are predominately in the purchasing currency creating a natural hedge to protect Gross Profit Margin. This contribution will become more significant as the additional launches in the remaining 114 countries occur over the next 2-3 years and drive sales growth in Rest of the World.

Other Income

Licensing Income, which are the milestone payments received from the out-licensing agreements we have in our Rest of World markets, are classified in the Financial Statements as Other Income. This was $0.8m (PCP $0.7m) with a combination of new out-licensing agreements commencing and milestone payments on existing agreements.

The balance of Other Income of $0.2m (PCP $0.3m) is the *Callaghan Innovation* growth grant that we receive on eligible research and development expenditure.

Operating Overheads

- **Research and Development** investment increased to $5.0m (PCP $4.3m), and in addition our 50% of the spend on *Pascomer* increased to $0.6m (PCP $0.2m). This is reported under joint venture equity accounting in the Financial Statements as required by GAAP.

  We are now well advanced in the clinical trial program we identified at the time of IPO and, as recently announced, we have successfully concluded our most significant clinical trial which was the Phase 3 for *Maxigesic IV.* The completion of this study, along with the *Maxigesic* Oral Liquid study, represents a significant amount of our clinical trial expenditure planned at IPO.

- **Selling and Distribution** expenses increased marginally to $12.8m (PCP $12.6m) in support of the strong revenue growth we are seeing in the over-the-counter channel in Australia.

- **General and Administration** expenses increased to $3.6m (PCP $3.1m) with increased international travel and legal fees primarily relating to out-licensing discussions, together with some additional increases in information technology which drive efficiencies.

Cash Flow and Balance Sheet

Total Assets of $50.4m are down on the March 2017 year end's $58.2m. This is mainly due to the investment made into research and development both directly and through the joint venture reducing the cash balance.

Working Capital increased slightly to $23.9m (PCP $23.1m) with the $2.4m increase in inventory to $21.1m (PCP $18.7m) for the stock build for the larger sales volumes during the summer months together, with the $1.2m reduction in trade payables and provisions to $13.8m (PCP $15.0m) which was largely offset by the $2.8m reduction in receivables to $16.6m (PCP $19.4m).

Cash holdings of $7.2m are down from the $16m at the March 2017 year end, primarily reflecting the investment made into research and development.

The long term CRG loan of $23.2m has a maturity date of 31 March 2020. There is a further draw down available of US$10m, with a mandatory US$5m to be draw down on or before 31 March 2018, and the balance available to be drawn at the option of the company on or before 30 September 2018.

Product Development

- ***Maxigesic*** is now being sold in ten countries – Australia, Brunei, Israel, Italy, Malta, New Zealand, Serbia, Singapore, United Kingdom and United Arab Emirates. Further country launches are in progress with exact timings dependent upon multiple factors around the finalising of the regulatory processes at a country and licensee level. These are either completing registrations or transfer of existing registrations to local licensees in Europe. Getting to launch requires a number of steps in each country and these timings are hard to forecast.

  Registration across almost all of Europe has been confirmed following referral procedure at the European Medicines Agency [EMA]. The remaining EU countries [Cyprus, Greece and Lithuania] will be finalised within the next 6 months. This is a significant achievement as it removes a large amount of regulatory risk from many of the remaining countries which in turn primarily rely upon the EU registration.

  Maxigesic is now licensed in 124 countries up from 110 in FY2017. Additional significant markets such as France - the second largest potential market in the world - have been added. Further countries are under negotiation which we anticipate will increase this number further.

  Although the sales of *Maxigesic* are yet to make a significant contribution to the sales revenue line, a significant number of key regulatory and licensing steps have been achieved over the last 6 months. These steps represent an essential precursor to sales.

  Clinical studies have progressed with successful completion of the key *Maxigesic IV* (intravenous dose form) study in USA and the *Maxigesic* Oral Liquid study in Australia, Mexico and New Zealand. Preliminary analysis of the *Maxigesic IV* study has confirmed that the study met the primary endpoints with a high degree of clinical and statistical significance. This is a significant achievement and has reduced the clinical trial risk for this product, which is a key factor for any pharmaceutical company involved in drug development. Dossier preparation is underway for both of these dose forms to meet filing targets.

  Development of three new *Maxigesic* formulations, in two cases utilising additional in-licensed technology, are currently well underway with these additional filings targeted within the FY19 year.

- **Product clinical studies** are on track with 10 being conducted in FY2018. Four studies have been completed, one study is ongoing and five studies planned to commence during the second half of FY18. The majority of the R&D program flagged in the original IPO document has now been completed, with the remainder about to commence.

- ***NasoSurf*** development is proceeding with the US Food and Drug Administration development pathway recently confirmed. Last year registration as a Class I Medical Device was completed. However the major market opportunities lie in indications covered by a Class II Medical Device registration pathway which is consequently the targeted opportunity.

  Manufacturing development work is also proceeding to plan.

  This FY2018 year, the clinical study program is well underway with one study completed in the US, one study underway, and a further two studies to start in the second half FY2018. A further two clinical studies will be required during FY2019 in order to move towards completion of the development program.

Outlook

Sales have grown well in the home market of Australia during the first half of the year. We anticipate Australia will continue to experience strong growth, particularly with the re-scheduling of codeine based painkillers from over-the-counter to prescription only from 1 February 2018. We anticipate the most significant changes to occur around the transition date although there is the potential for a degree of patient stock piling of codeine, which could delay the uptake of alternative analgesic products such as *Maxigesic.*

Although growth has been lower in New Zealand we have continued to transition sales to products in the over-the-counter market. We also expect growth to continue in New Zealand with some additional over-the-counter launches such as the newly registered *Maxigesic PE* which is a dose form of *Maxigesic* designed specifically to treat colds and flu. The loss of Metoprolol tender sales will, however, suppress this during the second half of the year.

The timing of Rest of World sales remains difficult to determine due to the multitude of countries and differing regulatory requirements and related timelines. There will be further launches prior to our March 2018 year end, although this number will be lower than previously thought due to slower regulatory transfers of the EU licenses, meaning that the revenue will be pushed into the FY2019 year. The estimates from licensees continues to indicate that the sales will increase significantly over the next two to four years with new launches, growth in already launched markets, and new line extensions.

The out-licensing programme is proceeding well with the key parameters being to increase registrations and launches in rest of world territories. Negotiations continue at term sheet and due diligence stages and a number of these are for more significant markets than previous agreements. Successful conclusion will generate significant upfront and milestone payments. It is not possible to predict exact timing accurately, but it is noted that AFT has a strong record in closing licensing deals.

The clinical trial programs are progressing well and remain on track, notably with the successful conclusion of the significant *Maxigesic IV* trial. The successful and timely completion of the remaining significant trials remains an important factor for the company. However the major *Maxigesic* tablet, IV and Oral Liquid studies have all been successfully completed lowering the associated clinical risk as these products will make up the bulk of the *Maxigesic* product sales going forward.

Although a number of studies are planned during the second half of FY2018 the costs are relatively lower, and again lower in FY2019 unless additional programs are pursued. However the focus is on completing already shadowed developments and achieving commercialisation prior to additional development programs.

Market research has identified that the *Nasosurf* project represents significant commercial opportunity. The device design and first manufacturing runs have been successfully completed, the

development program confirmed with FDA, the first study completed and others underway. Completion of this program in order to file the registration in major territories is now a major development focus given that the majority of the *Maxigesic* development has been completed.

We remain confident that we will return to profitability during the FY2018 or FY2019 time period. Timing will be dependent upon finalisation of a number of significant out-licensing agreements currently under negotiation.

[End of release]

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About AFT

AFT is a growing multinational pharmaceutical business with a broad range of products, both developed itself and in-licensed from third parties. AFT's products cover all major pharmaceutical distribution channels: over-the-counter, prescription and hospital. Historically, AFT's home markets have been Australia, New Zealand and South-East Asia. However the company is out-licensing its own products to licensees and distributors to sell in an increasing number of countries around the world. The company's intensive Research and Development programme forms the basis of its international sales strategy. For more information about the company, visit our website www.aftpharm.com.