

## AFT H1FY17 Results Announcement

AFT Pharmaceuticals Limited (NZX; AFT, ASX; AFP) today announced its half-year unaudited financial results for the period ended 30 September 2016 (**H1FY17**).

### Performance Highlights

- **Operating Revenues** of \$29.8m for the first half of FY2017 to 30 September 2016 (H1FY17) were up 1% over the corresponding six month period ended 30 September 2015 (PCP).
- **Operating Loss** of \$8.4m (PCP \$3.5m) increased due to increased investment in Research and Development, and the launch of additional promoted over-the-counter products into Australia and Singapore.
- **Maxigesic** is now being sold in six countries – Australia, New Zealand, Italy, United Kingdom, United Arab Emirates and Singapore. A further eight country launches are in progress.
- **Maxigesic** licenced in 111 countries, up from 98 at FY2016.
- **NasoSURF** development is on-track with engineering pilot batches in production and the first regulatory filing in the key US market planned for this calendar year.
- **Product Clinical Studies** on-track with 12 studies being conducted in FY2017.
- **Research and Development** investment in our key global products has increased to \$4.5m<sup>1</sup> for the six months (PCP \$2.4m) and represents 15% of Operating Revenue (PCP 8%).
- **Cash available** at 30 September 2016 of \$16.1m following investment in R&D and product launches. Tight control of fixed overheads is being maintained.

<sup>1</sup> 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		Change (\$)	Change (%)
	FY2017	FY2016		
<b>Revenue</b>	<b>29,787</b>	<b>29,543</b>	<b>+244</b>	<b>+1</b>
Cost of Sales	19,018	19,161	-143	-1
<b>Gross Profit</b>	<b>10,769</b>	<b>10,382</b>	<b>+387</b>	<b>+4</b>
Other Income	1,007	1,328	-321	-24
Selling and distribution expenses	(12,575)	(9,525)	+3,050	+32
General and administrative expenses	(3,135)	(3,302)	-167	-1
Research and development expenses	(4,276)	(2,406)	+1,870	+78
Equity Accounted Loss of joint venture entity	(210)	-	+210	++
<b>Underlying Operating Loss</b>	<b>(8,420)</b>	<b>(3,523)</b>	<b>+4,897</b>	<b>+139</b>

### Operating Revenue

Operating Revenue grew 1% to \$29.8m for H1FY17 from \$29.5m in the PCP with growth in all markets other than New Zealand:

- Australia Operating Revenue** grew 6% to \$14.6m (PCP \$13.8m) and this market now makes up 49% of the Group Operating Revenue. *Maxigesic* revenues have doubled over PCP with post rescheduling advertising which started in late August and is expected to drive further sales growth through H2FY17. The recent *Crystaderm*, *RestoraNail*, *ZoRub* and *Myconail* launches are looking promising at this early stage. The combination of these products together with strong hospital sales contributed to the 17% overall underlying growth. However, this was pulled back by 11% to the net 6% growth for the market as a whole by the low levels of production for a significant product in the first half. An additional factory for this product has now been commissioned and we are seeing improving supply levels going forward which should increase sales of the product in H2FY17. Additionally, a significant number of new hospital products are being launched in H2FY17 which will improve sales during the remainder of this and the next financial years.
- New Zealand Operating Revenue** declined by 10% to \$13.5m (PCP \$15.0m) and now represents 45.3% of the Group Operating Revenue. 4% of this decline was due to the manufacturing supply issues of the tender product Metoprolol (previously announced to the market). AFT continues to work with PHARMAC to ensure that the ongoing continuity of supply to patients is stabilized. The remaining 6% decline is due to weaker sales to the Pharmacy channel. Recently released market data on retail sales in Pharmacy indicates that

the market is down between 4% to 8% for over the counter and pharmaceutical products. Maxigesic sales made by AFT have been affected by this, however Maxigesic sales made by Pharmacy to customers are growing at a rate of 18% per annum. Sales of key over-the-counter (**OTC**) products are expected to improve during H2FY17 with significant seasonal promotional programs underway which are planned to retrieve the shortfalls of the first half.

- **Southeast Asia Operating Revenue** doubled to \$0.5m (PCP \$0.3m) with the launch of *Maxigesic*, *Crystaderm*, *Restoranail* and *Ferro* in Singapore. As with Australia these launches are at an early stage, however, the initial indications are that sales are progressing well.
- **Rest of World Operating Revenue** of \$1.2m overtook the full annual FY2016 Operating Revenue and grew 181% over the PCP \$0.4m. This now represents 4.0% of the Group Operating Revenue. Most of the sales were from *Maxigesic* sales to and royalties from the licensees in Italy and the United Arab Emirates. These and the United Kingdom licensees report sales well ahead of their expectations. Launches by our Licensees are imminent in eight additional countries.

### **Gross Margin**

Gross Profit of \$10.7m grew by 3% over the prior year (PCP\$10.4m) driven by the Operating Revenue growth primarily in Australia, supported by the growth in the Rest of the World and Southeast Asia and offset by the decline in New Zealand.

The Gross Profit Margin has risen to 36% (PCP 35%). This was driven by growth of the higher margin OTC products in Australia and the Rest of the World. The weaker New Zealand performance was further hindered by a \$0.4m provision against stock damaged in transit from a supplier which is subject to ongoing discussions with the company's insurers, supplier and logistics providers.

We expect the positive impact on Gross Margin to continue as the sales of OTC products in Australia and International revenues grow.

The strong NZ\$ has helped the gross margin to a small degree in Australia and New Zealand. The International sales tend to be in the purchasing currency creating a natural hedge to protect future gross margin swings.

### **Other Income**

Licensing Income, which are the milestone payments received from the out licensing arrangements we have in our 'Rest of the World' markets, are classified in the Financial Statements as Other Income. This was \$0.7m for the period (PCP \$0.9m), with a combination of new out licensing agreements commencing and milestone payments on existing agreements.

The balance of the other income is the Callaghan growth grant that we receive on eligible research and development expenditure. The growth grant does not allow expenses incurred offshore as eligible which has limited this support. By necessity much of our clinical trial program is required to be conducted off shore simply because New Zealand does not have either the patient base and/or the infrastructure and/or expertise for some of our trials. We work closely with the Callaghan Innovation in a number of other areas and we highly value the benefits that we have been able to achieve from our collaborations.

### **Operating Overheads**

- **Research and Development** investment increased to \$4.5m from \$2.4m in the prior year, with the accelerated investment in clinical trial spend enabled from our Initial Public Offering in December 2015. This includes the \$0.2m spend on *Pascomer* which under GAAP

accounting we are required to record as joint venture equity accounting in the consolidated Income Statement.

- **Selling and Distribution** expenses increased to \$12.6m (PCP \$9.5m) with the launch of OTC products in the Australian and Singapore markets plus the advertising of *Maxigesic* in Australia after a scheduling change which occurred on 1 July 2016. We anticipate good revenue growth in these products through to the end of the year following this initial investment in their launch.
- **General and Administration** expenses were flat at \$3.1m (PCP \$3.3m). Staff numbers were kept steady and fixed costs are under tight control.

### **Cash Flow and Balance Sheet**

Total assets of \$53.8m are down on the year-end's \$65.3m, largely due to the investment made into research and development and the launch of primarily established OTC products into Australia and Singapore. Working Capital requirements increased slightly with the \$3.8m increase in Inventory to \$21.4m primarily for the stock build up for the summer months, together with the \$0.6m reduction in creditors offset by the \$3.6m reduction in debtors to \$12.8m.

Cash holdings of \$16.1m are down from the \$28.0m at year end primarily reflecting the Profit and Loss related investment made into research and development and product launches. The balance sheet remains primarily working capital with the only intangible of significance being the \$2.5m of capitalised patents and trademarks.

The long term CRG loan has the option for further draw-downs which we have no current plans to exercise.

Total Liabilities lowered to \$35.8m from \$37.1m at the year-end due primarily to the favourable revaluation of the US\$ denominated term loan.

### **Product Development**

- **Maxigesic** is now being sold in six countries – Australia, New Zealand, Italy, United Kingdom, United Arab Emirates and Singapore. A further eight country launches are in progress. *Maxigesic* tablet sales in International Markets are performing ahead of expectations. Additionally further licensing agreements are under negotiation in significant territories. Completing these registrations and launches in licensed markets is key to extending *Maxigesic* sales. Clinical studies are progressing as planned with the key *Maxigesic IV* study underway in USA and for the additional dose forms. Additional technology has been licensed for new *Maxigesic* formulations the developments for which are currently underway.
- **NasoSURF** development is on track with engineering pilot batches in production and the first regulatory filing in the key US market planned for this calendar year. Device Clinical trials are also starting as planned with the first three studies due to start during H2FY17.
- **Research and Development** investment in our key global products has increased to \$4.5m<sup>1</sup> for the six months (PCP \$2.4m) and represents 15% of Operating Revenue (PCP 8%).

“We are pleased with progress in international out-licensing, clinical trials, and the *NasoSURF* device to date,” says AFT Managing Director, Dr Hartley Atkinson. “However the suppressed home market

(Australia and New Zealand) operating revenues, due to supply issues and the retraction of the NZ pharmacy retail market, have hindered growth that we will be working hard to recover in the second half.”

## **Outlook**

It is anticipated that sales growth in Home Markets will accelerate in H2FY17 with increasing OTC sales following recent launches and promotions, and the introduction of a significant number of new hospital products in Australia (where additional contracts for over A\$3m per annum have been secured). Significant seasonal promotional programs will be implemented in New Zealand and Australia consistent with prior practice. These are expected to drive sales during the second half of the year, which historically has always been greater than the first half due to seasonality.

The out-licensing program will continue to be utilised to increase registrations and launches in International Territories. Further licensing agreements are currently at term sheet negotiation stage and a number of these are for more significant markets than previous agreements. Successful conclusion will generate significant upfront and milestone payments. However the exact timing is not possible to accurately estimate.

Timing of International Sales is still very difficult to determine due to differing regulatory requirements and related timelines in the various international markets. However the estimates from licensees indicate that sales made by AFT are likely to increase significantly over the next 5 years.

Clinical development programs are progressing well and successful and timely completion remains a critical factor in achieving these estimates.

The *NasoSURF* development has progressed significantly during the last six months. The key parameter is to generate supportive clinical data for registration in the key US and EU markets. Following initial clinical trial results out-licensing will be initiated with negotiations planned to start in FY2018.

We remain confident in our plans and progress that we articulated during our initial public offer in December 2015 and continue to target a return to profitability during the FY2018 / FY2019 time period.

*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](http://www.aftpharm.com).