

## **AFT PHARMACEUTICALS**

Medium to Long Term Growth Objectives Presentation September 2016



## **IMPORTANT NOTICE**

This presentation has been prepared by AFT Pharmaceuticals Limited ("AFT"), to provide a general overview of AFT. It is not prepared for any other purpose and must not be provided to any person other than the intended recipient.

All amounts are disclosed in New Zealand dollars (NZ\$) unless otherwise indicated. All references to FY20XX appearing in this presentation are to the financial year ending 31 March, unless otherwise indicated.

This presentation is not a recommendation or other form of financial advice. While reasonable care has been taken in compiling this presentation, none of AFT nor its subsidiaries, directors, employees, agents or advisers (to the maximum extent permitted by law) gives any warranty or representation (express or implied) of the accuracy, completeness or reliability of the information contained in it nor takes any responsibility for it. The information in this presentation has not been and will not be independently verified or audited.

This presentation may contain certain forward-looking statements and comments about future events, including with respect to the financial condition, results, operations and business of AFT. These statements are based on management's current expectations and the actual events or results may differ materially and adversely from these expectations. Recipients are cautioned not to place undue reliance on forward-looking statements.

Past performance information given in this presentation is given for illustrative purposes only and should not be relied upon (and is not) an indication of future performance.

## **SUMMARY OF AFT BUSINESS and MEDIUM TERM GROWTH**



## Established Business [1997] and growing AU & NZ [19% CAGR Last 10 Years].

Significant further potential growth in AU

Growth in SE Asia: Growing business in Singapore & Malaysia. To start sales in Hong Kong within FY17

The most significant growth opportunity: Growing Key Innovative Products outside ANZ & SE Asia via Distributors & Licensees.

Maxigesic Tablets & Other Dose Forms

#### **Large Target Markets for Key Innovative Products**



Maxigesic Tablets – Target Market US\$10.4B Maxigesic IV – Target Market US\$832M Maxigesic other oral dose forms – Target Market US\$3.7B Maxiclear PE – Target Market US\$1B

#### Development NasoSURF Medical Device



Patented Ultrasonic Powered Drug Delivery Device Treatment Post-op Sinus Surgery & Chronic Sinusitis A Number of Drug Delivery Indications. First regulatory filings within 2016

## **CURRENT HIGHLIGHTS**

109

countries that *Maxigesic* is licensed in Further countries to license

6

countries that Maxigesic is launched and sold in

12

number of clinical studies AFT will have running in FY2017

\$65.8m

total income for FY2016\*

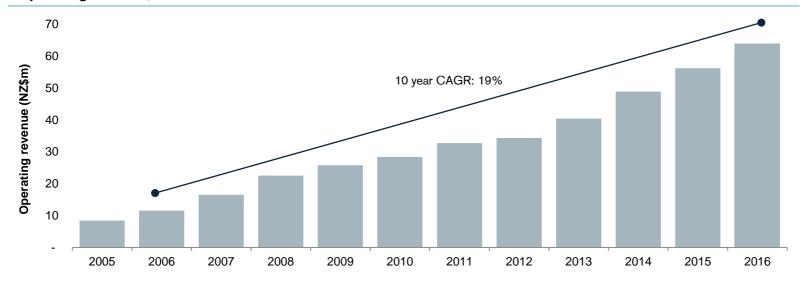
\$28.1m

available cash as at 31 March 2016

<sup>\*</sup> Total income comprises Operating Revenue of \$64.0m and Licensing Income of \$1.8m

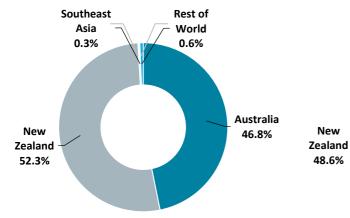
## FINANCIAL PERFORMANCE - REVENUE GROWTH

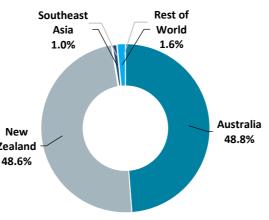
#### Operating revenue, FY2000 - FY2016



#### FY2015 Operating revenue by region

#### FY2016 Operating revenue by region





#### **Southeast Asia**

#### Singapore

10 approved products
12 more in registration
June/july launched 4 products

#### Malaysia

4 approved products13 more in registration

#### **Rest of World**

Increasing launches and filings.
Mainly Maxigesic but also others

UAE – additional two products to be launched during 2016

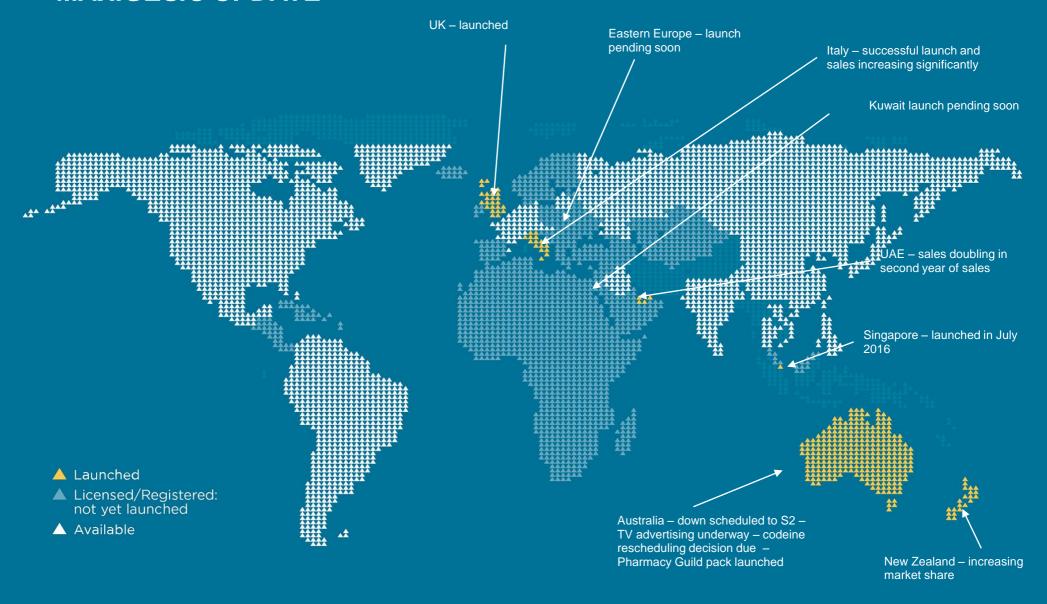
▲ F Tpharmaceuticals

Medium to Long Term Growth Objectives
Sep 2016

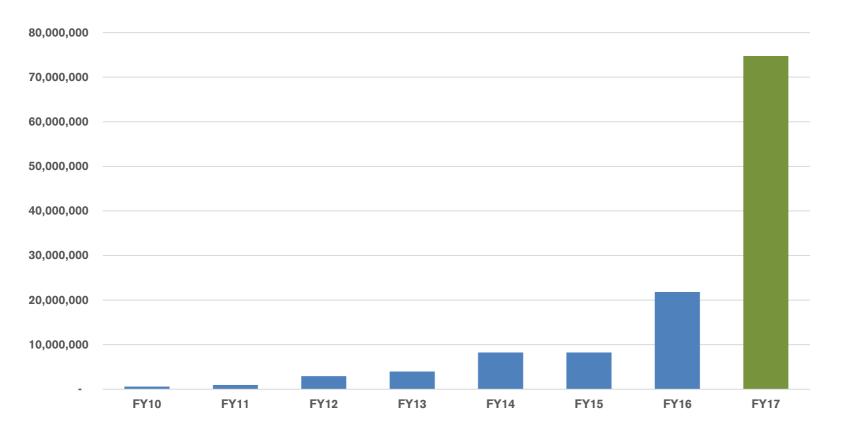
## **ACCELERATING CLINICAL STUDY PROGRAM**

- 12 studies across the AFT portfolio
- 1500+ patients
- 7 countries Australia, Jordan, Mexico, New Zealand, Russia, United Kingdom, United States
- Clinical Trials for *Maxigesic* oral dose forms are well underway with studies running in Amman,
   Jordan; various centres in New Zealand; Cardiff, Wales; Melbourne, Australia; Guadalajara; Mexico.
- An IND (Investigational New Drug) Application has been successfully opened with the FDA for
   *Maxigesic IV* and the first clinical study under the IND has been completed in Christchurch, New
   Zealand. The next study is planned to start in 2016 in the United States (Texas and Maryland).
- NasoSURF Device Clinical Studies to start in 2016
- Maxiclear PE pivotal study to be completed by the end of 2016

## **MAXIGESIC UPDATE**



## **MAXIGESIC TABLET SALES PROGRESS TO DATE**



Maxigesic Tablets Sold Per Year [FY17 sales estimates based upon actual first 5 months (33M tabs), current orders and licensee/AFT estimated orders for remainder FY17]

## **MAXIGESIC HIGHLIGHTS**

Additional out-licensing and distribution agreements for *Maxigesic* oral dose forms have been secured to increase the number of countries to 109 as at 31 August 2016.

Clinical Trials for *Maxigesic* oral dose forms are well underway with studies running in Amman, Jordan; various centres in New Zealand; Cardiff, Wales; Melbourne, Australia; Guadalajara; Mexico.

An IND (Investigational New Drug) Application has been successfully opened with the FDA for *Maxigesic* IV and the first clinical study under the IND has been completed in Christchurch, New Zealand. The next study is planned to start in 2016 in the United States (Texas and Maryland).

Regulatory applications for the first additional *Maxigesic* oral dose forms to be filed this FY2017 financial year.

Additional IP technology has been licensed to develop further *Maxigesic* dose forms. Development underway.

Additional out-licensing and distribution agreements for *Maxigesic IV* have also been secured to now reach 80 countries.

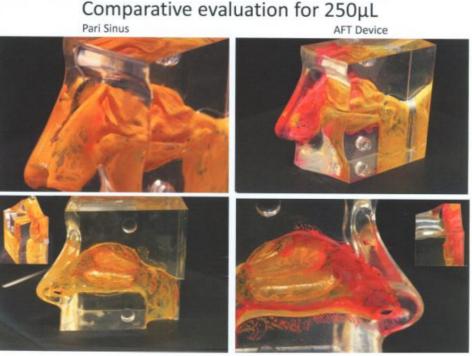
Additional out-licensing agreements, launches and registrations are expected to be announced over the rest of the FY2017 financial year.



### NasoSURF vs Pari Sinus

### **IntraNasal Distribution**





**▲ F** Tpharmaceuticals **Medium to Long Term Growth Objectives** Sep 2016

# NASOSURF NEBULISER DRUG DELIVERY AND TREATMENT SINUS CONDITIONS

Product description	A handheld ultrasonic nasal mesh nebuliser for the intranasal delivery of medication and treatment of chronic sinusitis
Rationale for investment in product	<ul> <li>To expand our existing allergy and hospital product ranges locally</li> <li>Significant global potential</li> </ul>
Current status	<ul><li>First filing on track for 2016</li><li>Pilot scale production underway</li></ul>
term plans	<ul> <li>FDA filing in preparation now for Q4 2016</li> <li>Distribution studies – healthy volunteers (Q3-4 2016)  – post-op sinus surgery patients (Q4 2016)</li> <li>Human Factor Studies Q4 2016 [new regulatory requirement]</li> <li>First Drug PK studies (Q4 2016 – Q1 2017)</li> <li>First Drug Clinical Studies (Q4 2016 – Q2 2017)</li> <li>Register a Class I medical device in USA (Q4 2016-Q1 2017). File Class IIa in EU Q1 2017</li> <li>Drug delivery use sales (Class IIa) late 2017 early 2018</li> <li>First drug delivery indication a significant potential</li> </ul>

research studies in USA and UK]

The Naso SURF Nebuliser has desirable features over currently marketed nebulisers, which are not approved for delivery of specific drugs intranasally and do not possess a number of the advantages of the Naso SURF Nebuliser



#### Sales will be generated from

- 1) device sales,
- 2) a per use charge administered through RFID (radio frequency identifier) cards, and
- 3) consumables

# NasoSURF Laboratory Set Up



## **SUMMARY OF MEDIUM TERM PLANS**



Launch Maxigesic in over 100 countries including North America

Additional Maxigesic regulatory filings and registrations

Add additional *Maxigesic* dose forms to the initial launches to extend the sales



Further licensing agreements including North America

Further licensing agreements for Maxigesic IV in major territories



Achieve first registrations for NasoSURF as a Medical Device

Licensing and sales in major target markets of North America and EU



Build revenues of OTC product sales in Australia

Build *Maxigesic* significant market share post scheduling changes and register and launch line extensions



Sep 2016

**Build Southeast Asia Business** 

Complete further registrations and launches