

# **AFT PHARMACEUTICALS**

Woodward Partners NZ Mid Cap Spotlight Presentation 12 April 2017

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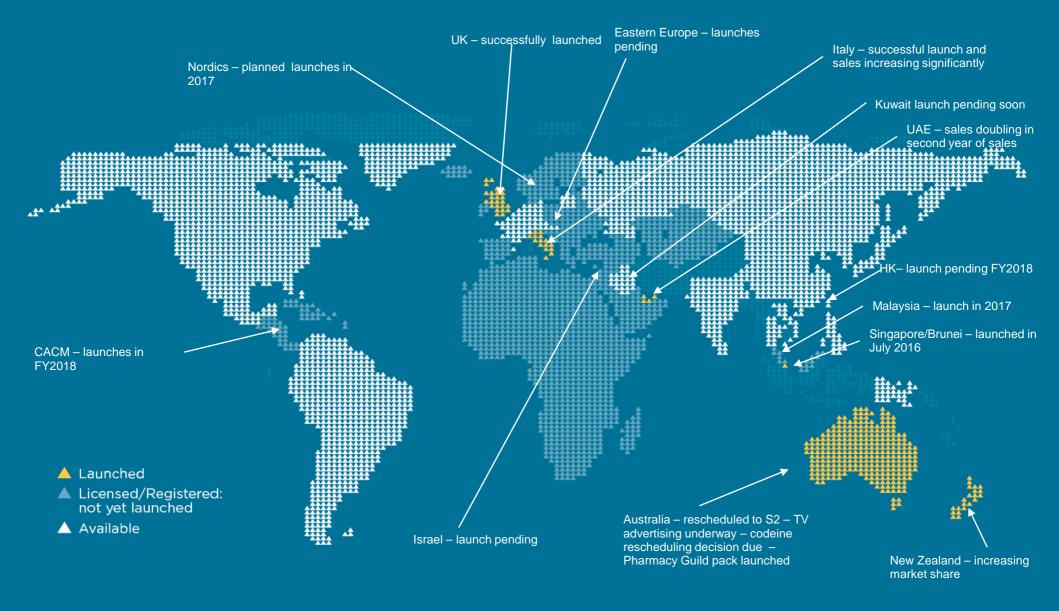
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# **PROGRESS UPDATE**

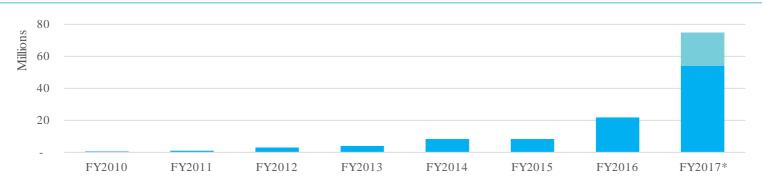
111	Countries that <i>Maxigesic</i> is licensed in – up from 98 at the end of FY2016. Negotiations underway for North America (MX & US/CA to follow) & EU	
6	Countries that <i>Maxigesic</i> has launched and is sold in with at least 20 further launches expected during this FY2018 year	
10	Number of studies AFT expects to complete during this calendar year – 8 Clinical and 2 Pharmacokinetic <i>Maxigesic</i> OL study and IV Studies close to closing.	
2	Additional dose forms of <i>Maxigesic</i> under development  – Dry powder sachets and Rapid Formulation Dry powder successful and moving to manufacture registration batches	
\$69 - 71m	expected total income for FY2017 [in the <b>upper end</b> of the range], up from \$65.8m in FY2016	
<b>\$7.6m</b>	available cash as at 28 February 2017 – down from \$16.1m at the end of H1 FY2017 and <b>prior to the recent \$9.1m raise</b>	

# **MAXIGESIC UPDATE**



## **MAXIGESIC SALES PROGRESS TO DATE**

#### Maxigesic Tablets Sold Per Year



- Maxigesic tablet sales for the FY2017 financial year are expected to increase to 74 million tablets per annum, representing a 339% increase on FY2016
- Additional out-licensing and distribution agreements for *Maxigesic* oral dose forms have been secured to increase
  the number of countries to 111 as at 30 September 2016, with additional out-licensing agreements expected to be
  negotiated during 2017, including in markets of significant size (e.g. the US, MX, CA, FR, DE)
- In Australia, Maxigesic can now be advertised directly to consumers and is more readily available in pharmacy stores. Also, the Australian regulatory authority confirmed the rescheduling of codeine OTC analgesics to become prescription medicines (from February 2018) which presents a significant opportunity for consumer conversion
- Sales in existing markets such as Italy, the UK and UAE have to date exceeded initial expectations. Sales in over 20 new countries (EU, CACM, Middle East, Asia) planned to commence in FY2018

## **MAXIGESIC AND AU CODEINE SWITCH**

#### CODEINE Market Research in AU ex MedPanel \* and Market Data

- 13M Maxigesic tablet sales for the FY2017 financial year in AU.
- 1Feb 2018 Codeine based OTC analgesics will be rescheduled to Rx
- 750M tablets of Codeine OTC Analgesics used in AU
- 70% will buy an alternative from their pharmacist
- 55% will seek advice from their pharmacist & 49% from their doctor
- 80% want a strong analgesic Maxigesic is the only paracetamol-ibuprofen combo stronger than both
  paracetamol or ibuprofen OTC dose
- 300 352M tablets most likely to switch
- 37% will switch some time before the 1 Feb18 date BUT 63% intend to wait

# NASOSURF NEBULISER DRUG DELIVERY AND TREATMENT OF 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 for drug delivery</li> <li>Sinusitis and Post Sinus Surgery to be established with clinical data (in vitro shows vastly improved sinus penetration cf. standard therapies)</li> </ul>		
Current status	<ul> <li>Engineering batches under production now</li> <li>Registered with the FDA in the US as a Class I Medical Device</li> <li>Clinical studies now commenced, with completion expected during the next 12 – 15 months</li> </ul>		
Our near term plans	<ul> <li>A p-IND Application will be made with the FDA in the first half of 2017</li> <li>Distribution studies         <ul> <li>healthy volunteers in calendar year 2016-2017</li> <li>Patients in calendar years 2017-2018</li> </ul> </li> <li>Conscious sedation PK studies calendar year 2017</li> <li>Conscious sedation clinical studies start calendar year 2017</li> <li>Licensing negotiations planned for FY2018, including in the US once some clinical data has been generated and the FDA development pathway finalised</li> </ul>		

The NasoSURF 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 NasoSURF Nebuliser



# Sales will be generated from:

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

# **OTHER KEY INNOVATIVE PRODUCTS**

Products	Status	
Pascomer (originally called Pascaderm)	Pascomer currently being developed, with an IND Application to be opened in US during FY2018 to enable clinical studies to be undertaken  Successfully obtained ODD from FDA. EMA under application after successful	
	meeting  FDA meeting scheduled completed March 2017 and development plan agreed  Market studies by US development partner indicate potential for key indication of	
	US\$600-800M, mid to high teens royalties and significant milestones. Note AFT share is 50%  Licensing negotiations for the US and EU markets have been initiated during 2017	
Maxiclear PE	Maxiclear PE now licensed in 21 countries with the pivotal Phase 3 study currently underway in Cardiff, Wales, and was expected to be completed by the end of Q1 2017 but will need to be completed in NZ winter (Q3 2017)	
Fibroleve	Registration underway in Malaysia as first country	
Crystaderm	Successfully launched in AU Under Registration in Middle East Study completed in Russia and filing preparations underway	

## **SUMMARY BALANCE SHEET**

NZ\$000's	Restated Unaudited as at 30 Sep 2016	
ASSETS		
Current assets		
Inventories	21,451	15,072
Trade and other receivables	12,748	12,224
Cash and other equivalents	16,054	10,016
Current income tax asset	19	113
Total current assets	50,272	37,425
Non-current assets		
Property, plant and equipment	421	449
Intangible assets	2,450	1,853
Deferred income tax assets	490	45
Derivative assets		917
Investment in joint venture entity	177	<del>-</del>
Total assets	53,810	40,689
LIABILITIES		
Current liabilities		
Trade and other payables	11,131	9,684
Provisions	1,841	2,326
Derivative liabilities	745	<u>-</u>
Total current liabilities	13,717	12,010
Non-current liabilities		
Interest bearing liabilities	22,039	24,721
Total liabilities	35,756	36,731
Equity		
Share capital	53,902	21,736
Retained earnings	(36,637)	(17,748)
Share options reserve	182	-
Foreign currency translation reserve	607	(30)
Total equity	18,054	3,958
Total liabilities and equity	53,810	40,689

- AFT has maintained very tight control of fixed overheads
- AFT had \$7.6m cash as at 28 February 2017, down from \$16.1m as at 30 September 2016 and prior to the recent \$9.1m raise.
- AFT's cash balance increased to approximately \$16.8m once NZ\$9.2m of redeemable shares are issued

## **SUMMARY OF NEAR TERM PLANS**



Launch Maxigesic in new countries and increase sales



Advance Maxigesic registrations in licensed countries and in North America



Complete remaining clinical studies of Maxigesic products over FY2018



Naso SURF – complete first clinical trials and first Class IIA regulatory filings
Undertake first licensing negotiations



Build further revenues of new OTC products launched in Australia Increase *Maxigesic* sales especially from Codeine rescheduling



Break even targeted in the FY2018/FY2019 time frame from increased higher margin product sales in home markets; increased licensing income from existing and new agreements, especially in larger markets; increased *Maxigesic* sales



The company believes it has secured sufficient funds to deliver on its plans.