Market release

16th January 2017

2017 New Year Letter to Investors

Dear investors,

The 2016 calendar year was a very busy one for AFT Pharmaceuticals.

Our primary focus has been the continual advancement of our *Key Innovative Projects*, as well as our higher margin over-the-counter (OTC) products in the Australian market. Targeted growth like this naturally incurs costs, but we have maintained tight control over our expenses throughout the year.

Although the contributions of advancing these projects are not yet apparent in the current financial results, progressing them is important as we are laying the building blocks for future material growth in AFT sales and earnings.

To recap, key projects are:

(1) **Growing *Maxigesic* sales in all markets**

Tablet sales for the FY2017 financial year are expected to increase to 74M tablets per annum. This is a 339% increase on the prior year.

Currently *Maxigesic* is licensed in 111 countries. This means we have negotiated and signed contracts with specialist companies to market and distribute *Maxigesic* in these countries. We have launched in six countries with additional launches pending within the next 12 months. A key work in progress is to increase these launches and thus sales.

Additional licensing agreements in markets of significant size, for example the United States, are aimed to be negotiated in the next 12 months pending successful progress of regulatory applications through the US Food and Drug Administration. Larger markets will also generate more significant upfront licensing payments and subsequent milestones in addition to greater sales.

Sales in existing markets such as Italy, the UK and UAE have to date exceeded initial expectations of the licensees which, if carried through to other new markets, will be positive.

In Australia, two important regulatory decisions in 2016 landed in AFT's favour. First, *Maxigesic* can now be advertised directly to consumers and is more readily available in pharmacy stores (previously it had to be stored behind a pharmacist's counter).

Second, just before Christmas, the Australian regulatory authority confirmed an interim decision that codeine OTC analgesics will be rescheduled to become prescription medicines (from February 2018). As a codeine-free product, *Maxigesic* will not require a prescription and so we expect an upswing in sales as people switch from codeine-based painkillers.

Both regulatory decisions offer significant growth opportunities. These decisions have added significance because they are in the key Australian market where AFT sells products itself (rather than through a distribution agreement with another company) and consequently gains a larger return of top line sales.

(2) **Other *Maxigesic* dose forms**.

Maxigesic is currently only sold in tablet form. However good progress is being made with additional *Maxigesic* dose forms.

In-licensed technology has enabled the successful development of a new *Maxigesic* formulation. Based upon development work completed to date, this is anticipated to offer additional clinical benefits and an improved IP position. More details will be announced in future as the development continues.

A further development has also been started for a formulation that can be taken without water. This *Maxigesic* formulation would be suitable for use in countries where clean water is not readily available such as North Africa. *Maxigesic* is licensed throughout Africa, North Africa and the Middle East so it is expected that this new dose form will be popular in these markets.

These projects have resulted in some additional expenditure. Nonetheless the attraction of seeking an extended IP position was considered to be important and therefore worth the additional unbudgeted spend.

The key *Maxigesic* IV (intravenous) development is on track with the successful opening of an Investigational Drug Application with the US Food and Drug Administration. Patient enrolment into the pivotal study taking place within the US is also advancing well.

Further licensing negotiations and agreements are planned during 2017 for this *Maxigesic* IV project and significant upfront payments and milestones will be sought.

Other *Maxigesic* dose forms remain on track with the first filing planned around the end of 1Q 2017.

(3) ***NasoSURF* Development**

Our patented *NasoSURF* device has progressed with registration in the US achieved on schedule as a Class I medical device.

Our market research in the USA and EU has identified the most attractive indication to pursue, with a market sales potential of US$1.2 billion in the US alone. This will require additional clinical studies, and an Investigational Drug Application will be made with the US Food and Drug Administration in the first half of 2017.

The first clinical studies are commencing now with the aim to complete these studies during the next 12-15 months. We also intend to initiate licensing discussions for some major markets, including the US, within the next 12 months.

The performance of the device to date continues to confirm the initial results presented prior to AFT Pharmaceuticals' IPO (December 2015), and offers a key driver of revenue once the *NasoSURF* has been successfully commercialised.

Once significant progress of the first indication has been achieved, development of further identified indications will be initiated.

(4) *Pascomer*

Pascomer is a novel treatment applied to the skin to treat certain serious skin conditions.

A number of indications are available for this co-development with a US based company. The first indication has been chosen and is currently being developed. An Investigational Drug Application will be opened in the US during 2017 to enable the pivotal clinical study to be undertaken.

The formulation has used our proprietary technology to successfully formulate a stable topical version which is challenging to achieve as the active ingredient is unstable.

Potential peak sales in the US and the EU for this initial indication of US$600-800M have been estimated pending pricing and successful completion of the pivotal clinical study.

Licensing negotiations for USA and the EU markets will be initiated during this 2017 year which, if successful, would be expected to generate significant upfront licensing payments and milestones in the short term with royalties in the medium term.

(5) Australia

AFT continues to work on growing sales of higher margin OTC products with a number of launches already made in this current financial year (FY2017). Sales are not immediately apparent as it takes time to gain distribution at a retail level. This was particularly evident during 1H FY2017.

Additionally, due to high promotional costs, a positive contribution to earnings will not be apparent until sales increase. However significant progress has been made and based on the sales growth we expect from these new products, we anticipate that contributions after variable costs (marketing, distribution and co-op) will grow significantly in FY2018. It is not planned to increase fixed costs to any significant degree with the major investment in our sales team already made in FY2016.

A key sales upside in Australia is the potential conversion of consumers from OTC codeine to alternative analgesics such as *Maxigesic.* Currently 750 million tablets of OTC codeine analgesics are sold each year in Australia.

We anticipate that many of these consumers will switch to codeine-free analgesics rather than visiting a GP for a prescription to purchase a codeine-

based product (which will be the new requirement from February 2018 across all states in Australia). We are fortunate to have considerable internal expertise in running 'switching campaigns', and the consumer switch away from codeine in Australia will be a major project for AFT this year.

To get a better idea of the number of people likely to switch as a result of this change, AFT has just received the results of market research with codeine consumers in Australia undertaken by US-based market research firm *Medpanel*[1].

The research has estimated that 40 to 47% of current consumers would seek an alternative pain reliever from their pharmacies and are thus potential candidates for switching to *Maxigesic.* This represents a potential 300 to 352 million tablets of *Maxigesic.*

Prior to the re-scheduling of codeine-based analgesics, our growth estimates were for sales increasing in Australia from 13 to 26 million tablets in FY2018. However the codeine re-scheduling offers significant additional sales potential and even gaining a relatively small proportion of the available 300 to 352 million tablets, identified by the market research, would result in a significant sales upside.

It should be noted that the market research does identify that the majority of any upside will only occur at the time of the re-scheduling i.e. February 2018. We also want to stress that it is likely only a proportion of the identified target consumers would switch to *Maxigesic* and further work is underway to quantify this potential upside.

Outside of our key development projects, we have experienced some manufacturing difficulties with two products that are known to be challenging to manufacture. However, these products are lower margin and consequently contribute less to profit. In our view, the overall outlook is on track pending further successful registrations and clinical outcomes for the *Key Innovative Products*.

This said, it is important to note that our development program is deliberately varied, to enable diversification of development risk and future revenues. Our experience tells us that diversification is something that cannot be underestimated in the pharmaceutical business.

AFT has been profitable for almost all of our 19 year history, so resuming profit is always a key aim. The exact timing of break-even is dependent mainly on *Maxigesic* sales growth in current and new markets, and the timing of larger licensing deals which in particular remain difficult to forecast with accuracy.

We continue to target break-even within the FY2018/2019 financial years. However the current losses are also necessary in order to rapidly advance both development of *Key Innovative Products* and Australian OTC product launches in a timely manner.

We thank you for your support. I hope you can see that as the founder I have retained my entire shareholding post-IPO and have no current intentions to sell down which in turn reflects my personal confidence in our prospects going forward.

Best regards

Hartley Atkinson

CEO and Founder

AFT Pharmaceuticals Ltd

Phone: +64 9 488 0232

Footnote 1. Market research of 100 codeine consumers in Australia conducted by *Medpanel*, MA 02138, USA. Estimated error is +/-9%