



9 January 2024

NEW YEAR LETTER TO INVESTORS

## **AFT poised to accelerate momentum in 2024**

Dear shareholder,

As the new year commences, AFT Pharmaceuticals is looking forward to building upon the significant progress made during 2023. Last year we moved on from the uncertainties of the COVID-19 pandemic and we are pleased with the progress we made, especially in our international markets.

We were also pleased to finalise two US FDA regulatory approvals for the intravenous and rapid dissolving tablet forms of our Maxigesic<sup>®</sup> pain medicine (Maxigesic IV and Maxigesic Rapid) and to achieve a regulatory approval in China for our antiseptic skin cream Crystaderm<sup>®</sup>. Going forward, these medicines should help to further drive International sales.

Our focus presently is primarily upon sales growth, and we were pleased that again good progress is being made, as evidenced by the 24% growth in product sales and 27% growth in overall revenue, reported recently for the 1H FY24 results. This followed on from the 30% product sales growth reported for the 1H FY23 result.

Last year we highlighted we foresaw proportionally greater strength in International sales as we put the pandemic behind us. Pleasingly this is now playing out, with sales outside Australasia growing by 94% for the 1H24 period.

We reiterate we believe our international markets offer the largest potential upside in our performance over the next few years and we continue to aggressively pursue this growth opportunity.

However, it is also important to note that our home Australasian, Asian and UK businesses also continue to offer strong prospects. Our focus on laying the foundations for growth in these markets has seen the conclusion of 104 product in-licensing agreements (counting one drug and one country as an agreement).

These agreements have also seen a strengthening of our relationships with long term partners such as Edge Pharmaceuticals, London, and Hyloris Pharmaceuticals, Belgium. We are also proud to be working with New Zealand entities, such as Massey Ventures and the Gillies McIndoe Research Institute, and we hope to extend these relationships.

## **International**

A key goal for the New Year is working towards the launch of Maxigesic IV and Maxigesic Rapid in the US market, the world's largest for pain relief<sup>1</sup>, following last year's landmark regulatory approvals. Stocks of Maxigesic IV have now been manufactured and Hartley is off to the US later this month to train the sales force of our US Maxigesic IV licensee Hikma Pharmaceuticals.

We have launched the Maxigesic Cold & Flu/Sinus & Pain kit in our Australasian markets and will explore further markets outside Australasia. We also continue to work on regulatory approvals for Maxigesic Rapid, Maxigesic Dry Stick Sachets and Maxigesic Day & Night in markets around the world. In some markets such as Belgium we have gained approval to reclassify the oral dose forms of Maxigesic as OTC medicines (as opposed to the original prescription classification). Further reclassifications are in progress and we believe this new approach will accelerate sales in these markets.

We continue to build the international infrastructure we discussed in last year's newsletter.

We now have a team of four staff, including an experienced CEO, in our UK office in Whitechapel, London. AFT Pharmaceuticals UK is well positioned to take advantage of regulatory rule changes aimed at fast-tracking medicines with Australian or Singapore registrations. It is handling the launches of Maxigesic tablets as an OTC medicine in the Boots pharmacy chain and Maxigesic IV in UK hospitals. The UK business is also working on a growing UK product pipeline.

We are meanwhile recruiting a staff member expert in quality assurance to our AFT Pharmaceuticals Europe office in Ireland, delivering a capability fundamental to operating as a fully functional pharmaceutical company in the European Union.

We are seeing additional opportunities in both Europe and the UK now that we have established offices in these markets. A recent example is our acquisition of a license in one EU market for a medicine discontinued by a multinational R&D company. We will pursue regulatory approvals for the medicine in a number of other EU markets, with a focus on the most significant. In the immediate term we plan to sell the medicine on an unlicensed basis whilst pursuing regulatory approvals. This type of opportunity would never have been apparent without a physical presence in these markets.

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<sup>1</sup> Mordorintelligence.com. 2021. Pain Management Market (2021 - 26) | Industry Analysis, Size, Share | Covid - 19 Impact.

It is important to temper growth expectations in these markets. As we have demonstrated in our Australasian markets, pharmaceutical sales usually build gradually over several years, but can rise to be substantial over time.

There are of course exceptions to this rule. We have, for example, seen strong demand and rapid sales growth in Korea for Maxigesic IV. Korea is generally regarded as an early adopter so this should in turn bode well for other markets where sales continue to grow albeit at a more modest rate.

### **Australia and New Zealand**

AFT is continuing to work hard to accelerate sales momentum in both Australia and New Zealand. We have bedded down our new 11-strong doctor-focussed sales force in Australia. We see this as an important step for the Australian market.

We hit some regulatory delays in Australia, but we still plan to launch a total of 20 products during the FY24 financial year, a figure slightly down on the 23 launched last year. Overall, our pipeline for the FY24-26 period has expanded to 73 planned launches. This program, including international in-licensing, has resulted in additional investment for in-licensing fees.

In Australasia, we also invested heavily in product promotion, which weighed somewhat on the 1H24 result, but we remain confident that an aggressive growth focus will achieve the best long-term results.

### **E-Commerce**

AFT continues to work on expanding its e-commerce offerings both in Australasia and Internationally. We stress this strategy is not to compete with our primary customers, rather it assists to boost our brand presence. In Australia we have launched an AFT Amazon site which is performing to expectations.

The first major e-commerce project in international markets was the Cross Border E-Commerce (CBEC) site via Tmall China. It is progressing well, and we are seeing good growth in sales overall.

Internal e-commerce in China represents a much larger opportunity than the CBEC channel and represents an attractive platform for the launch of Crystaderm this year, following its regulatory approval last year.

We have additionally launched an Amazon site in the USA which we will keep working on growing and to which we will add additional products over time.

### **Research and Development**

Our research and development programme is the most complex part of our business, both to undertake and to explain to investors.

The key point to note is that it provides the foundations for future growth and is therefore essential to consolidating our position in our Australasian markets and most significantly, extending our presence in international markets. The launch of Maxigesic in international markets represents a foothold rather than the 'endgame'.

Additional development opportunities have continued to come available assisted by the tight global financing conditions which have impacted biotechs and companies looking for capital for drug development projects. As we have mentioned previously AFT profitability means we are well positioned to both acquire new projects and fund them from our existing cashflows.

In 2023 we added three new projects to our R&D pipeline:

- an antibiotic eye drop for treating drug resistant eye infections licensed from a US company;
- a topical treatment for strawberry birthmarks licensed from New Zealand's Massey Ventures; and
- a treatment for burning mouth syndrome, a cooperation with Hyloris Pharmaceuticals, our existing Maxigesic IV development partner.

All these projects offer significant upside. Additionally, we are evaluating and discussing three further projects which, if concluded, would further deepen AFT's R&D pipeline to expand its international business over the next years alongside our aggressive in-licensing program.

The antibiotic eye drop project is advancing well with preliminary work largely completed. This year we will file a pre-Investigational New Drug (pre-IND) application with the US FDA, a meeting to agree the final preclinical development requirements before starting clinical studies.

Our strawberry birthmark project has advanced to plan with great work conducted by the team at Gillies McIndoe to identify the key most synergistic ingredients for the patented topical treatment. This work has been made possible by innovative *in-vitro* cell line testing work. We have started formulation development and similarly are working towards a pre-IND application with the US FDA.

For our *NasoSURF* project, we are working through the identified device problems which relate to dose delivery uniformity, so this project has progressed slower than targeted last year. Market research for the first indication indicated a potential US billion-dollar product so the project remains of high interest.

We completed our Pascomer clinical study in the rare disease, Facial Angiofibromas (FAs), and we are also starting a pilot study to investigate the potential efficacy in the treatment of Port Wine Stains after laser treatment.

We have completed the formulation development works for the tablet and sachet formulations of our "Project KW" gastroenterology medicine and we are targeting the completion of regulatory dossiers later this year.

The third formulation for the KW project may be delayed as the recent R&D pipeline additions offer stronger commercial propositions. Regardless, the estimated addressable global market is significant at around US\$700M. We are targeting the commencement of sales of the first two formulations in some of our markets towards the end of this year.

We have completed the dossier for our second gastroenterology medicine, "Project BT", and will commence regulatory filings soon this year.

We have meanwhile secured regulatory approvals for our "Project SD" dermatology medicine in China and Canada and are preparing for launches during this year. A key concern has been securing sufficient stock to supply these markets, especially China, so additional manufacturing sites are being added.

### **Financial outlook**

Overall, we continue to work hard to execute upon our plans and look forward to building on the significant progress made during the last 2 years. We are particularly excited about the multiple key business advances outside Australasia we see coming to fruition in the coming year.

With pandemic-related restrictions and delays in supply chains easing we have begun to delay some product purchases in order to decrease stockholdings although the unfolding situation in the Red Sea continues to suggest a prudent approach to seaborne goods shipped from Europe.

We have continued to focus primarily on growth with ongoing significant investments in product promotions, in-licensing, R&D and building our sales hubs in Singapore, Hong Kong, and the UK and Europe.

The FY24 result will be significantly influenced by the timing of the lumpy licensing income associated with the launch timing of Maxigesic IV in USA. We continue to work with Hikma, to execute this launch within FY24 which, if achieved, will result in around NZ\$6 million being booked to our FY24 profit, but this cannot be guaranteed.

We thank shareholders for their ongoing support and look forward to reporting progress against these goals when we release our results for FY24 in May.

With our best wishes for the year ahead.

Kind regards

David Flacks  
Chair

Dr Hartley Atkinson  
Managing Director

*For and on behalf of AFT Pharmaceuticals Limited by Malcolm Tubby, Chief Financial Officer.*

### **For more information:**

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### **About AFT Pharmaceuticals**

AFT is a growing multinational pharmaceutical company that develops, markets, and distributes a broad portfolio of pharmaceutical products across a wide range of therapeutic categories which are distributed across all major pharmaceutical distribution channels: over the counter (OTC), prescription and hospital. Our product portfolio comprises both proprietary and in-licensed products, and includes patented, branded, and generic drugs. Our business model is to develop and in-license products for sale by our own dedicated sales teams in our home markets of Australia and New Zealand and in certain Southeast Asian markets, and to out-license our products to local licensees and distributors to over 125 countries around the world. For more information about the company, visit our website [www.aftpharm.com](http://www.aftpharm.com).