# AFT Pharmaceuticals Ltd

**Share Price: NZ$3.62**

**NZX: AFT, ASX: AFP**
**Sector: Health Care**
**5 August 2022**

## Broadening horizons

AFT Pharmaceuticals (ASX: AFP / NZX: AFT) has begun FY23 with no shortage of news flow. As we reported in our 25 May 2022 note, it recorded a strong result for the 12 months to 31 March 2022 (FY22), making $130.3m in annual operating revenue (up 15.2%), a $20.4m operating profit (up 91%) and a $19.8m net profit (up 154%). It is expecting an operating profit for FY23 between $27m and $32m and to pay its inaugural dividend to shareholders.

### Launching OTC medicines in China

The biggest news so far in FY23 was the launch of the first New Zealand OTC (Over The Counter, without prescription) online pharmacy store in China, in partnership with RooLife Group (ASX: RLG). AFT had partnered with RLG back in July 2020 to deliver the online health store Kiwi Health Store in China and launched it in October 2020, initially with a trial range of AFT's health supplements. The Kiwi Health Store is now approved for sale to OTC pharmaceuticals and provides the company with exposure to the world's second largest ecommerce market.

### What now for Pascomer?

On 27 July, AFT announced the analysis of its clinical study of Pascomer. Although the study found that Pascomer delivered statistically significant benefits against relevant indicators, it fell short of the threshold on the IGA scale that the FDA considers necessary for registration in the United States. Timber Pharmaceuticals has terminated its agreement with AFT and AFT will continue development work alone. The company retains its European licensee Desitin Arzneimittel and believes it has potential for facial angiofibromas (FA) and other non-orphan indications. An initial study in 'Port Wine Stain' birthmarks is due to start in Spain.

### Maxigesic FDA application a Work In Progress

AFT is also attempting to have Maxigesic IV approved in the USA. Last month, it received a Complete Response Letter (CRL) requesting more information. The company is confident it can deliver the required information to the FDA to obtain approval but we note it is already registered in 37 countries and launched in 7.

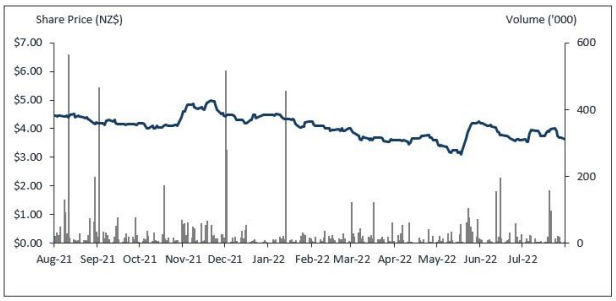
### Valuation of NZ$6.92 per share

In our previous note on AFT from May 2022, available *here*, we valued AFT at NZ$6.92 per share in the base case and NZ$9.59 per share in the bull case, using the DCF model. We reiterate this valuation.

| | |
|---|---|
| Market Cap. (NZ$ m) | 379.0 |
| # of shares outstanding (m) | 104.7 |
| # of shares fully diluted (m) | 104.7 |
| Market Cap Ful. Dil. (NZ$ m) | 379.0 |
| Free Float | 26.7% |
| 52-week high/low (NZ$) | 4.99/3.10 |
| Average NZX daily volume (k) | 33.1 |
| Website | aftpharm.com |

*Source: Company, Pitt Street Research*

**Share price (NZ$) and avg. daily volume (m, r.h.s.)**




*Source: Refinitiv, Pitt Street Research*

| Valuation metrics | |
|---|---|
| Valuation per share (NZ$) | 6.92-9.59 |

*Source: Pitt Street Research*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## Kiwi Health Store on Tmall Global expanded

*AFT is now selling its OTC pharmaceuticals range*

Last month, AFT Pharmaceuticals and RooLife Group (ASX:RLG) announced it has launched the first New Zealand OTC online pharmacy store in China, on Tmall Global. The companies already launched the online pharmacy store (Kiwi Health Store) in China, initially with a trial range of AFT's health supplements. Under the deal, AFT provides its portfolio of products for sale, while RLG offers its digital marketing, store operation and sale of AFT's portfolio of products.

Following strong support, it is now selling its OTC pharmaceuticals range, thanks to China's CBEC OTC scheme that authorises AFT Pharmaceuticals' registered medicines to be sold to Chinese consumers. The range will be expanded over the next few months, but the company has declined to give estimates as it is too early to make reliable conclusions. Nevertheless, it is an important milestone because the store is the first New Zealand direct-to-consumer TC online medicine marketplace on Tmall Global. Products carried include: Vitamin C Lipo Sachet, Vitamin D Lipo Sachet, Ferro Sachet, Kiwisoothe, Crystawash Extend, Loraclear hay fever relief and Histaclear non droswy allergy relief. AFT will extend its OTC medical product portfolio, which will include Maxigesic and five additional OTC medicine products.

**Figure 1: The Kiwi Health Store**


*Source: AFT Pharmaceuticals*

## China is a significant market

*The Chinese market for OTC medicines is the world's second largest behind the US.*

The Chinese market for OTC medicines is the worlds second largest behind the US and is growing rapidly. In 2020, it was worth US$16.3bn and is expected to reach US$22.7bn by 2023. This is due to the ageing of the

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*COVID restrictions posed challenges, but the company was helped by the easing of restrictions.*

population, an increased focus on healthcare and increased uptake of ecommerce – over 58% of OTC medicine sales in China occur online.

Local investors have been bearish towards companies with any exposure whatsoever to China in light of tensions between Australia and China. But remember, this is a New Zealand company. New Zealand products remain popular with Chinese consumers and we consider it unlikely that any trade war will develop that might put this market at risk.

## The promise of Pascomer

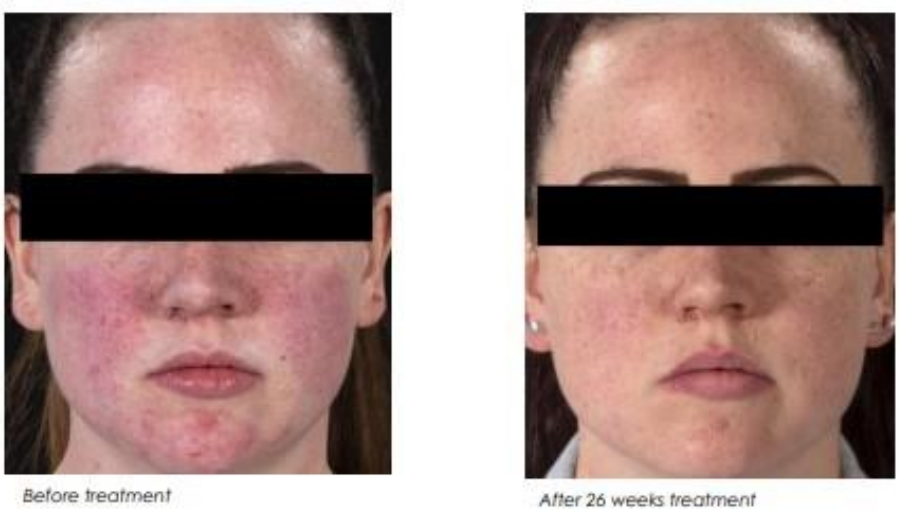
While the company has much to look forward to in the future, launching 78 new in-licensed products over the next 3-4 years, we are particularly excited about Pascomer.

Pascomer is an orphan drug built on an active ingredient called rapamycin. It is designed to treat rare skin conditions including facial angiofibromas (FA) in Tuberous Sclerosis Complex (TSC). TSC is a rare genetic disorder that causes benign tumours to grow in various parts of the body. 75% of TSC patients tend to develop FA, which impairs patients' facial appearance and reduces their quality of life. Management estimates that this affects around 30,000 patients in the US and 50,000 patients in Europe.

Of all the products in AFT's R&D pipeline, Pascomer has been the most advanced with two licensing agreements – with Timber Pharmaceuticals for North America and Desitin Arzneimittel GmbH for Europe – and it has undertaken a multi-centre global clinical trial for Pascomer. The goal of that trial was to ascertain te optimal dose at which hthe drug demonstrates biological activity with minimal side effects.

On 27 July, AFT annunced it completed the study. The study showed Pascomer delivered statistically significant [P<0.05] benefits against the clinically relevant Investigators Global Assessment (IGA), Facial Anglofibroma Severity Index (FASI) and patient-physician improvement scales.

**Figure 2: Example of a 1-point change in the IGA scale over the study period**




*Source: AFT Pharmaceuticals*

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## Is the dream over?

However, the medicine did not reach the threshold on the IGA scale that the US Food and Drug Administration (FDA) considered necessary for its registration in the United States (US) as a treatment for FA. AFT also announced it had terminated its agreement with US licensee Timber Pharmaceuticals. We also observe that Japan's Nobelpharma secured FDA approval for a treatment for FA, which effectively blocked entry into the US market for 7 years anyway given the orphan drug status held by Nobelpharma's asset – making it likely that even if the trial had met the thresholds, the deal may not have proceeded. So what now?

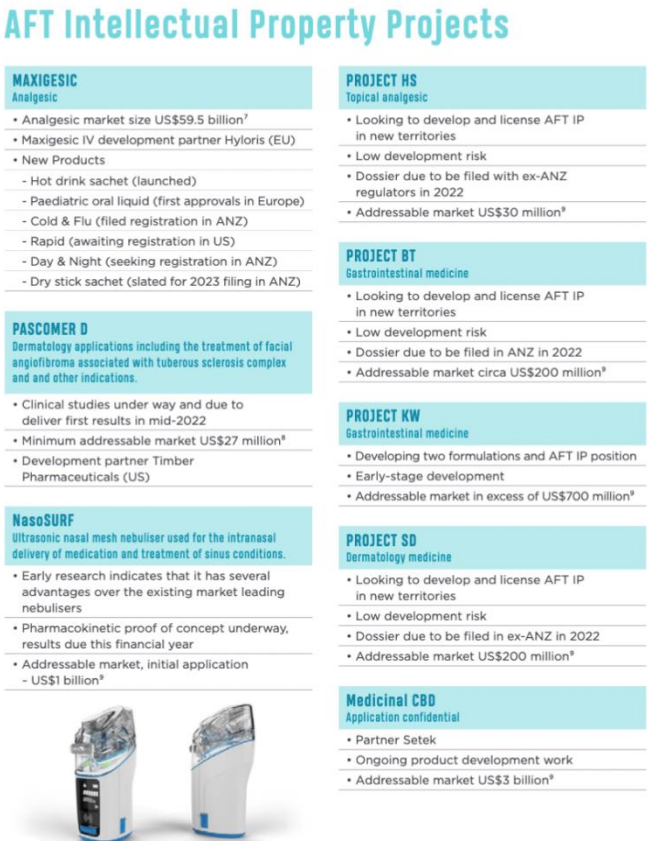
***AFT still believes in Pascomer, retaining its European licensing deal, and believing it could help with non-orphan indications.***

The company believes that it still shows promise even though it fell short of FDA thresholds. This is both for FA but also in certain non-orphan indications which might be more significant markets and would not require the company to either be the first market or miss out for 7 years.

AFT retains its licensing deal for Europe with Desitin Arzneimittel GmbH and plans to launch a new study in Spain examining the potential of Pascomer for 'port wine stain' birthmarks. This is a skin condition affecting 3 in every 1,000 children that, just as its name implies, appears as if someone spilled wine on the skin.

AFT's Pascomer assets had a carrying value of $12.5m which the company has not changed. And, the next R&D and commercialisation activities could be well accomodated in the company's existing R&D budget, ~$12m for FY23. Again, we note that the company is launching 78 new in-licensed products over the next 3-4 years, so there is potential for the company to bring more products to market.

**Figure 3: AFT Pharmaceuticals' Intellectual Property Projects**




*Source: AFT Pharmaceuticals*

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## Maxigesic still not in the US, but in dozens of other markets

Another setback with the FDA occurred in relation to Maxigesic IV. The US regulator issued a Complete Response Letter (CRL) requested additional data on one remaining issue. It is important to note that this is not an outright rejection – as happened to Lumos Diagnostics (ASX:LDX) recently. However, it is not an upfront approval as shareholders inevitably hoped for. The company remains confident that it can deliver the FDA the information required to approve the medicine.

***Although the US approval eludes Maxigesic, the tablet was sold in 47 countries while the IV form is registered in 37 countries and is launched in 7.***

And even though the US is the world's largest healthcare market, it is not the only one, neither is it a market the company is gambling its entire hopes on. As we noted in our 27 May 2022 update, AFT offered its Maxigesic tablets in 46 countries as at the end of FY22 and anticipates it can reach 63 in FY23. And Maxigesic IV is registered in 37 countries and has been launched in 7, with Australia, Germany and Korea being 3 of them.

**Figure 4: Countries where Maxigesic is sold and ordered**


*Source: FY22 Investor Presentation*

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## Valuation

*Our share price target range is NZ$6.92-$9.59 per share.*

In our research initiation on AFT from November 2021, available here, we valued the company at NZ$6.09 per share in the base case and NZ$9.29 per share in the bull case, using the discounted cash flow model. In our most recent update from May 2022, available here, we updated our valuation to NZ$6.92 in the base case and NZ$9.59 in the bull case. We reiterate this share price target range. We kept our growth forecasts unchanged but adjusted certain inputs rush as the risk-free return.

Our base case assumes Maxigesic tablet enters 10 new countries a year to FY25 and 5 from FY26 to FY28. Our bull case assumes 15 per year until FY26 and 5 per year to FY28. By FY28, our base case forecasts 99 countries while our bull case forecasts 114 countries. However, we have not modelled beyond FY28 because the company's patent will expire.

With Maxigesic IV, we have assumed a 30% market share in our base case and a 40% market share in our bull case, although full ramp up and AFT's reaching of the maximum market share only occurs in FY27. For Pascomber, our base case assumes a 50% market share and a 10% royalty payable while our bull case assumes a 60% market share and a 12% royalty. Again, we have assumed ramp up occurs gradually over the next few years, reaching 100% by FY23. For both Maxigesic IV and Pascomber, we have assumed a constant market size over the life of our model - US$2.1bn for Maxigsic IV and US$500m for Pascomber.

Our base case is NZ$6.92 per share (previously $6.09) and our new bull case is $9.59 per share (previously $9.29). It is important to note that we are using the company's NZX listing for the purpose of our share price targets, given the lower liquidity on the ASX.

**Figure 5: DCF valuation summary**

| Valuation | Base Case | Bull Case |
|---|---|---|
| Present value of FCF | 759.4 | 1,038.4 |
| Present value of Terminal FCF | - | - |
| **Enterprise Value (NZ$M)** | **759.4** | **1,038.4** |
| Net debt (cash) | 35.2 | 35.2 |
| **Equity value (NZ$)** | **724.3** | **1,003.2** |
| Share outstanding | 104.7 | 104.7 |
| **Implied price (NZ$)** | **6.92** | **9.59** |
| Current price (NZ$) | 3.62 | 3.62 |
| *Upside (%)* | *91.2%* | *164.8%* |

*Estimates: Pitt Street Research*

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## Catalysts

We have identified the following near-term events as important facilitators of moving the current stock price towards our fair valuation range:

- Sales growth from its OTC pharmaceuticals range
- Better-than-expected global uptake of the Maxigesic family of products;
- Obtaining regulatory approvals and registrations for new countries; and
- Unveiling a new timeline and development plan for Pascomer.

## Risks

We see the following as key risks to our investment thesis:

- **Uptake risk:** There is a risk that AFT may not be able to gain traction in its target markets. There is no guarantee that AFT and/or its distributors will be able to secure a specific number of purchase orders for its existing and new products. In addition, the launch of new products may receive lower-than-expected uptake from customers. If this risk materializes, AFT will likely report financials below our forecasts. In turn, this will hamper our valuations.
- **Clinical risk:** The clinical studies for Pascomer could potentially produce unfavourable results, which would delay the commercialization timeline for the product.
- **Competition risk:** There is the "what if" scenario where new and/or existing competitors coming up with superior and cheaper products that seek to address the same market opportunity set as AFT. If this risk materializes, it can hamper AFT market share growth and margins.
- **Commercial risk:** To be able to distribute and/or sell its products in any country, AFT will first need to register its products in that country. There is a risk that AFT may not obtain entry in that market.
- **Currency risk:** AFT buys goods and services from offshore suppliers. This exposes AFT to foreign currency risk.

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## Appendix I – Analyst Certification

Nick Sundich, lead analyst on this report, is an equities research analyst at Pitt Street Research

- Nick obtained a Bachelor of Commerce/Bachelor of Arts from the University of Sydney in 2018. He has also completed the CFA Investment Foundations program.
- He joined Pitt Street Research in January 2022. Previously he worked for over three years as a financial journalist at Stockhead.
- While at university, he worked for a handful of corporate advisory firms.

Stuart Roberts has been an equities analyst since 2002.

- Stuart obtained a Master of Applied Finance and Investment from the Securities Institute of Australia in 2002. Previously, from the Securities Institute of Australia, he obtained a Certificate of Financial Markets (1994) and a Graduate Diploma in Finance and Investment (1999).
- Stuart joined Southern Cross Equities as an equities analyst in April 2001. From February 2002 to July 2013, his research speciality at Southern Cross Equities and its acquirer, Bell Potter Securities, was Healthcare and Biotechnology. During this time, he covered a variety of established healthcare companies, such as CSL, Cochlear and Resmed, as well as numerous emerging companies. Stuart was a Healthcare and Biotechnology analyst at Baillieu Holst from October 2013 to January 2015.
- After 15 months over 2015–2016 doing Investor Relations for two ASX-listed cancer drug developers, Stuart founded NDF Research in May 2016 to provide issuer-sponsored equity research on ASX-listed Life Sciences companies.
- In July 2016, with Marc Kennis, Stuart co-founded Pitt Street Research Pty Ltd, which provides issuer-sponsored research on ASX-listed companies across the entire market, including Life Sciences companies.
- Since 2018, Stuart has led Pitt Street Research's Resources Sector franchise, spearheading research on both mining and energy companies.

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