PITT STREET RESEARCH

AFT Pharmaceuticals Ltd

Much more room for growth

Share Price: NZ$4.83

NZX: AFT, ASX: AFP
Sector: Health Care
19 November 2021

We initiate coverage on AFT Pharmaceutical (NZX: AFT, ASX: AFP) with a fair valuation range of NZ$6.09 – $9.29 per share. AFT is a profitable and founder-led pharmaceutical company that develops, licenses, distributes and sells a wide range of pharmaceutical products globally. Its product portfolio has >100 proprietary products that have applications in multiple therapeutic areas including pain relief, eye care, skin care and digestive health. AFT's lead asset is Maxigesic, a repurposed drug that combines two OTC painkillers, namely paracetamol and ibuprofen, that offers fast and effective pain relief. Since commencing its first sales in New Zealand in 2009, AFT is now commercialising Maxigesic in >40 countries.

Investment case

We believe AFT provides a strong growth story underpinned by its differentiated products and a capital light global rollout strategy. We think Maxigesic has a stronger value proposition when compared to some of the traditional painkillers, as its composition excludes any use of opioids. And since Maxigesic is built on two standalone painkillers and therefore benefits from drug synergies, it offers more effective pain relief than the individual ingredients. We think this value proposition is sustainable and should help AFT to win share in the global markets. Moreover, AFT has created an injectable form of Maxigesic, named Maxigesic IV, which we expect to drive sales in the post-operative pain management market.

Valuation of NZ$6.09 per share

Our valuation range for AFT is NZ$6.09 – $9.29 per share. This is based on a risk adjusted DCF model that incorporates expected sales, earnings and cashflows from AFT's three lead assets: 1) Maxigesic tablet, 2) Maxigesic IV, and 3) Pascomer. Refer to page 19 for key risks to our investment thesis.

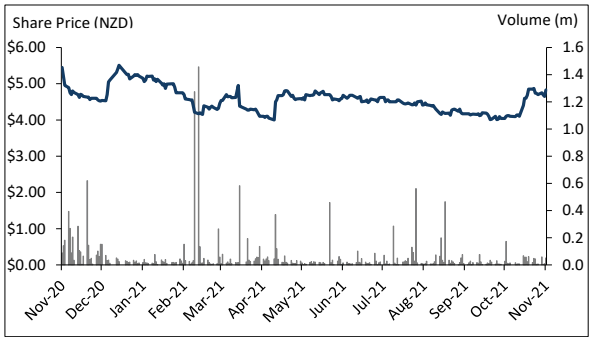
Year to March (NZ$)	FY20a	FY21a	FY22e	FY23e	FY24e
Sales (m)	105.6	113.1	133.9	187.8	277.3
EBITDA (m)	22.3	11.8	21.5	40.1	69.1
Net Profit (m)	12.7	7.8	16.9	24.0	43.7
EPS	0.13	0.08	0.16	0.23	0.42
DPS	0.58	0.18	0.00	0.00	0.00
EV/Sales	5.1x	4.8x	4.0x	2.9x	1.9x
EV/EBITDA	24.2x	45.8x	25.1x	13.5x	7.8x
P/E	37.0x	64.1x	29.9x	21.1x	11.6x

Source: Pitt Street Research

Market Cap. (A$ m)	505.5
# shares outstanding (m)	104.7
# share fully diluted	104.7
Market Cap Ful. Dil. (A$ m)	505.5
Free Float	26.7%
12 months high/low	5.55 / 4.00
Average daily volume (m)	0.1
Website	aftpharm.com

Source: Company, Pitt Street Research

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



Source: CommSec, Pitt Street Research

DCF	
Fair value (NZ$ per share)	6.09 – 9.29

Source: Pitt Street Research

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Introducing AFT Pharmaceuticals

Company overview

AFT Pharmaceuticals (NZE: AFT, ASX: AFP) is a global pharmaceutical company whose securities are dual listed on both the NZE and the ASX. Throughout this report, we will use AFT to denote the company.

AFT develops, licenses, distributes and sells a diverse range of pharmaceutical products across the globe. It also in-licenses products from third parties for sale in certain markets. As such, its product portfolio is highly diversified and offers patented products for use in multiple therapeutic areas including pain, eye care, skin care, allergy, digestive health and medicated vitamins.

AFT employs a drug repurposing approach at developing its product portfolio. This means focusing R&D effort at improving existing products with new and innovative enrichments rather than pursuing higher risk drug development of new molecular entities. The resultant repurposed medicines will help address patient needs and thereby improve patient health.

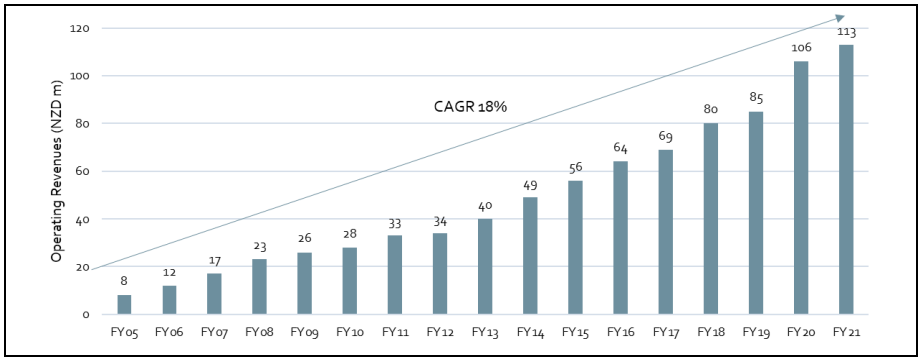
A founder-led business since 1998

AFT was founded as a small Kiwi business in 1998 by the pharmacologist Dr. Hartley Atkinson and his wife Marree. AFT began its journey as an importer and distributor of medicines on the New Zealand market, although it quickly expanded to develop its own products. In 2005, the company achieved its first sales in Australia. By 2009, after years of vigorous R&D and clinical trials, AFT successfully launched its first breakthrough product, known as Maxigesic, which is a repurposed drug that combines two popular OTC analgesics, namely paracetamol and ibuprofen, into a unique patented formulation. Importantly, Maxigesic had been clinically proven to provide more effective pain relief than the individual ingredients. Since 2009, AFT has scaled globally through rolling out Maxigesic into new markets, reaching 49[1] countries by March 2021. During this time, AFT has also continued to invest heavily in R&D, which subsequently resulted in its launching of new products and line extensions, more of which we will discuss in the section below.

AFT has been a consistent long-time steady organic grower over the past 16 years, delivering a sales CAGR of 18% over the FY05 – FY21 period (Figure 1).

AFT is an Atkinson-family controlled business, with the founders retaining c.70% of the stock and remaining actively involved in the business. We highly value a founder-led business because we think founders actively think about their business and foster an innovative company culture which we think is critical for a pharmaceutical company to succeed.

Figure 1: AFT's historical operating revenues profile



Source: Company, Pitt Street Research

[1] Maxigesic tablet form has been registered in 49 countries by 31 March 2021.

Maxigesic is only one of AFT's many products

AFT runs a broad portfolio of >100 proprietary and in-licensed products that have applications in seven core therapeutic areas (Figure 2).

Based off its initial Maxigesic formulation, AFT has further innovated it and created a family of line extensions (dose forms) including Maxigesic Oral Liquid and Maxigesic IV (intravenous or otherwise known as injectable form). In our view, this continued product innovation and R&D success are valuable because it not only extends the life of AFT's Maxigesic family patents but also diversifies AFT's revenues as well as the sales channels that AFT distributes its products through.

Further, AFT also has a strong product pipeline, of which it contains two new products, namely Pascomer and NasoSURF. Pascomer is an orphan drug that targets rare facial skin conditions, whilst NasoSURF is a hand-held nebuliser for the intranasal delivery of medication. As of now, Pascomer is progressing ahead of NasoSURF, with management expecting to finalise a clinical trial for the product in the near future.

Figure 2: AFT product portfolio profile

	Pain	Eyecare	Vitamins	Allergy	Digestive Health	Skincare	Hospital
Products	Maxigesic, ParaOsteo, ZoRub OA/HP, Fenpaed, Combolieve Day/Night	Hylo, Novatears, CromoFresh, Opti-soothe Wipes/Mask, VitAPOS	Ferro-liquid, FerroTab, Ferro-F, Ferro-sachets, Lip VitC, CalciTab	Loraclear, Histaclear, Fexaclear, Levoclear, Allersoothe, Lorapaed, Becloclear, Steroclear	Gastrosoothe / Forte, LaxTab, Micolette, Nausicalm, DiaRelieve	Crystaderm, Crystawash Extend Hand Sanitizer, Crystasoothe, ZoRub anti-chafing, Decazol, MycoNail, RestoraNail, Hemptuary, Pascomer	Maxigesic IV, Injectables, NasoSURF
Markets	Global for Maxigesic, with the other products mainly in Australasia	Australasia	Australasia and mainly Asia	Australasia	Australasia	Global for Crystawash Extend; Pascomer primarily targeting North America & Europe	Global
Distribution channel	OTC, Hospital	OTC	OTC	OTC	OTC	OTC, Prescription	Hospital
Stage of development	Developed	Developed	Developed	Developed	Developed	Pascomer in development	NasoSURF in development

Source: Company, Pitt Street Research

Figure 3 displays AFT's wide range of pharmaceutical products, many of which have been commercialised in the global markets.

Figure 3: AFT products

Source: Company

An enviable long-term track record in bringing new products to market

When examining a pharmaceutical company, we focus on three key aspects:

1) the strength of its product pipeline;
2) its track record of successfully taking new products to market; and
3) the capability and credibility of its management team.

We have touched on AFT's product pipeline earlier and we will dive into their respective markets later in the report. For now, we want to emphasise on the importance of a strong pipeline. This is because a new drug patent typically has a 20-year term before generic producers are allowed to enter the market and compete for market share through lower pricing. We believe AFT can mitigate this impact by:

- constantly innovating and developing new products and line extensions, which would effectively prolong AFT's patent terms and as such, enable AFT to continue generate a sustainable level of sales and earnings; and
- building Maxigesic into a strong brand that resonates with customers around the globe. We expect AFT to cement Maxigesic's OTC market position during the term of its patent[2], after which we expect customers to continue purchase Maxigesic despite the influx of generic drugs.

Importantly, AFT has built a long-term track record of successfully taking its new products to market. Figure 4 shows the large incremental increase in the number of products sold by AFT between FY08 and FY21, almost doubling in size. This implies that AFT has: 1) a proven ability to continually develop and launch new products, and 2) a track record of obtaining regulatory approvals to bring these new products to market.

We think these great outcomes are due to AFT having a capable and visionary founder-led management team who we believe have made the appropriate R&D investment over the past several years (Figure 5).

Figure 4: Number of AFT products

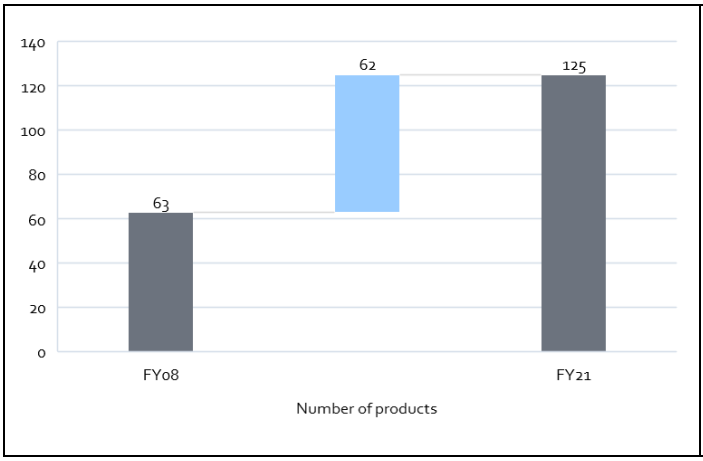
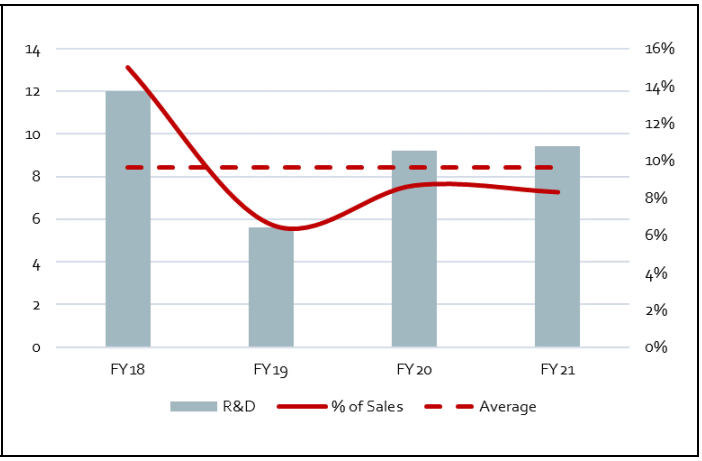


Figure 5: AFT R&D vs Sales profile



Source: Company, Pitt Street Research

[2] Maxigesic tablets are patent protected out to 2025-2028. We note there are other variants including intravenous (IV) that has a patent term out to 2037.

Unwrapping AFT's business model

AFT don't directly sell their products to consumers. Instead, they distribute their products through three major pharmaceutical channels: OTC, hospital and prescription.

i. Direct sales model

AFT has dedicated teams of their own sales staff in Australia and New Zealand and in certain Southeast Asian markets such as Singapore and Malaysia. So, AFT leverages their expertise to sell both its own and in-licensed products to these end-markets. Typically, AFT sells their products to licensed wholesalers who then on-sell them to customers such as pharmacies, optometrists, and public and private hospitals. In this case, AFT generates revenue from the sale of products but also bears the associated marketing cost.

ii. Out-licensing model

With regards to markets outside their home markets, Singapore and Malaysia, AFT employs an out-licensing model, in which AFT licenses their products to third party licensees and distributors who will then sell those products in their markets through their own sales channels. This sales model has a number of advantages: 1) cost efficient as the licensees/distributors pay for all the costs related to sales and marketing, 2) capital-light as AFT avoids paying for the large upfront capex and opex required to set up its own sales force in those other global markets, and 3) AFT can leverage licensees/distributors' existing networks and expertise in their local markets. On revenues, AFT receives: 1) licensing income which are one-off milestone-based fees, 2) product sales, and 3) royalties. If AFT has success in building scale in those foreign markets, we expect to see a ramp-up in forward earnings as most of royalty revenues should fall straight into the bottom line.

A global roll-out strategy to drive near/medium term sales and earnings

Having successfully developed, clinically tested and registered its products in many major markets, AFT is well-placed to capitalise on the sizable market opportunity ahead of it. As the heavy-lifting and riskier R&D process had been completed on those products, AFT's investment case is de-risked, in our view.

To illustrate this in an analogy: AFT recently built a 100-story skyscraper but has only rented out 5 floors so far. The residual 95 floors represent the incremental revenues and earnings that AFT could potentially earn, should it be able to drive its product uptake in the international markets.

We will now turn to AFT's market opportunity as well as share our view on why we think AFT's products will likely win shares in their end markets.

Pain relief

AFT's diversified product portfolio, coupled with its global footprint, imply a large total addressable market (TAM) opportunity. While we acknowledge the market potential may be substantial, we also note that it's difficult to drill down and quantify the size of every niche market segment that AFT services. As such, in this report, we will focus on the TAM of AFT's lead assets, namely Maxigesic, Pascomer and NasoSURF.

Market size

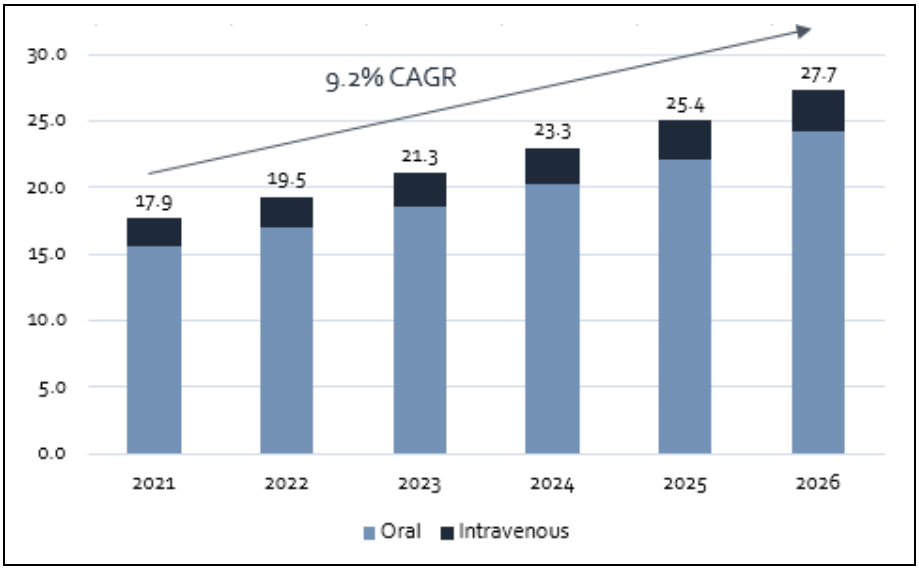
What is the market potential for Maxigesic?

In our view, the TAM for analgesic, also known as pain relief, can be divided into two categories, which are non-operative pain and post-operative pain. Non-operative pain is unrelated to surgery and is often dealt with by taking a painkiller in an oral dosage form. Whereas post-operative pain relates to pain after surgery and is mostly treated by an intravenous route of administration.

According to Research and Markets, the global TAM for analgesic is estimated to be US$17.9B in 2021, with an expected 5-year CAGR of 9.2%. Management estimates that the oral and intravenous dose forms constitute around 87% and 12% of the TAM respectively. We have used this as a proxy for estimating the market potential for both dose forms between 2021-2026e (Figure 6). For instance, in 2021, on a global basis, we estimate that the revenue for oral dose form would be around US$15.6B, whereas the revenue for intravenous form would be roughly US$2.1B. Given the assumptions made, we note that these may not be definitive revenue estimates, but we simply want to illustrate the magnitude of the market opportunity for analgesic.

We believe the key driver that underpins analgesic's long-term market growth is a growing and ageing population, which reflects increased risk of aches and pains. Near term, we also see a tailwind that results from a backlog of elective surgical procedures that have built up over COVID, which we expect to drive demand for the intravenous form of analgesic. And we think Maxigesic IV has the potential to capitalise on this opportunity.

Figure 6: Global analgesic market size by administration, 2021-2026e (USD bn)



Source: Research and Markets, Pitt Street Research estimates

Market structure

A fragmented but innovative industry

Maxigesic competes in a fragmented industry, with numerous pharmaceutical companies developing and providing pain medication/treatment. To name a few in the post-operative space, they include Pacira Pharmaceuticals, Hyloris Pharmaceuticals, Heron Therapeutics and Avenue Therapeutics.

Pain-relieving analgesics can be classified based on their mechanism of action:

- paracetamol, also known as acetaminophen;
- opioids;
- NSAIDs, stands for non-steroidal anti-inflammatory drugs which include aspirin, ibuprofen and naproxen; and
- combination analgesic products.

According to DelveInsight, opioids, NSAIDs and anesthetics currently hold the largest share in the postoperative pain market. Opioids are medicines derived from opium compounds that provide pain relief, such as codeine, oxycodone, hydrocodone and morphine. While opioids medications are widely used in the industry, their side effects and risks are widely known and reported and these include euphoria, addiction and nausea. As such, the industry has seen a rise in demand for better pain treatment options that possess high efficacy versus opioids but lesser side effects and drug dependency. In our view, Maxigesic is one such option with a strong value proposition that could potentially disrupt the opioid analgesic market. We will elaborate on this later in the report.

Figure 7 shows a few non-opioid analgesics and their brand names/owners. The industry has also seen a number of new entrants offering an alternative form of analgesic such as Durect Corporation's recently FDA approved Posimir and Heron Therapeutics' Zynrelef. We believe the rise of these new therapies is due to: 1) technological advancement and increased R&D investment, and 2) market's interest and demand for superior diagnosis and treatment options for pain management. Arguably, this market backdrop should bode well for Maxigesic, though we are also cognisant that increased competition may also impede Maxigesic's market share growth.

Figure 7: Classification of non-opioid analgesics

	Brand names	Brand owners
Paracetamol	Tylenol, Panadol	McNeil Consumer Healthcare, GlaxoSmithKline
Ibuprofen	Advil, Motrin, Nurofen	Pfizer, McNeil Consumer Healthcare, Reckitt Benckiser
Naproxen	Aleve	Bayer HealthCare
Combinations	**Maxigesic, Maxigesic IV**	**AFT Pharmaceuticals**
Alternatives	Exparel, Zynrelef	Pacira Biosciences, Heron Therapeutics

Source: DelveInsight, Wikipedia, Pitt Street Research

Maxigesic's market position

Our estimates tell us that AFT's management has done a remarkable job in growing the market share of Maxigesic in its home markets

AFT commenced its first sales of Maxigesic in Australia in 2014. Back then, AFT estimated that it achieved a market share of 0.5% (Figure 8). For 2021, we estimate that AFT currently holds a 9.2% market share in the Australian OTC market (Figure 9).

To derive our market share estimate, we first multiply AFT's FY21 Australian revenue by 62% to work out revenue generated by the OTC channel, which equates to A$42.3M. Absent product revenue breakdown, we then assume 80% of this revenue is attributable to Maxigesic sales, owing to Maxigesic being AFT's lead asset. This gives us A$33.9M, which we then divide it over a TAM of A$367M[3] to arrive at 9.2%. Our numbers are based off our assumptions and therefore don't reflect definitive market share estimates. But we think it's important to provide an indication of Maxigesic's market position in Australia.

Clearly, AFT has been successful in driving the take up of its Maxigesic tablet product in Australia. By being an early mover in rolling out a paracetamol-ibuprofen combination analgesic, AFT has arguably cemented its Maxigesic's OTC position in the market. As such, we believe AFT has built a strong brand positioning that resonates with local customers. Moreover, we think this will likely provide AFT a degree of pricing power, which would be valuable after Maxigesic tablet's patent expires in 2025-2028.

On New Zealand, AFT has similarly grown its share in the market, evident in its sales growth over the past several years (CAGR of 4% since 2018).

While Maxigesic has somewhat established its presence in Australia and New Zealand, we note that both these markets aren't static and still have plenty of growth ahead. We believe AFT's rollout of new products and line extension such as Maxigesic IV will expand its market opportunity. In turn, this should propel near/medium term growth for the company, in our view.

Figure 8: Maxigesic Australia OTC market share in 2014

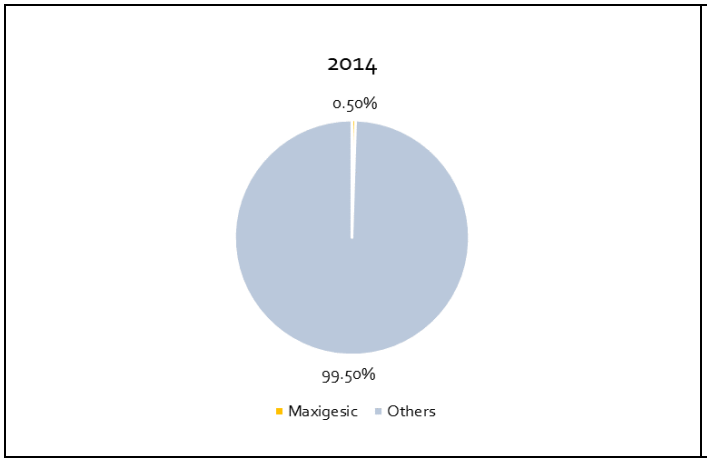
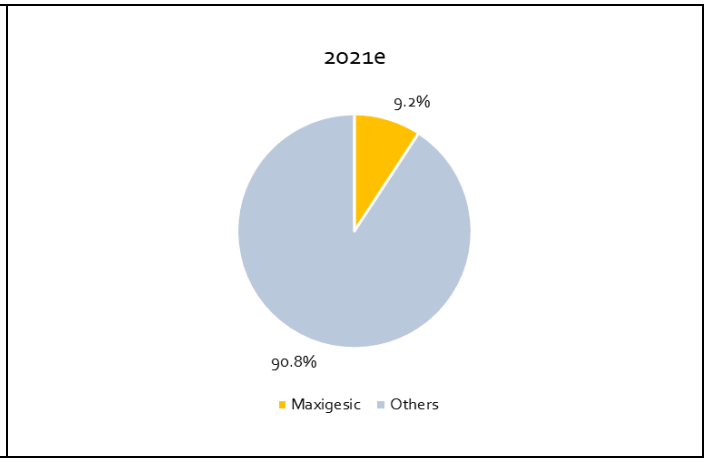


Figure 9: Maxigesic Australia OTC market share in 2021e



Source: Company, Pitt Street Research estimates

[3] AFT's Prospectus provided a market size of US$275M for Australia's paracetamol and/or ibuprofen analgesic pharmacy for 2014. This had been referenced from IMS World Review Pack (August 2015) to reflect the TAM for Maxigesic tablets in Australia. For simplicity, we assume the same market size holds true for 2021. Using an USD/AUD of 0.75, we estimate a market size of A$367M.

The big money is in the offshore international markets, and we view AFT as well-equipped to reap the reward

In our previous section, we have illustrated the size of the TAM for analgesic on a global scale. Based on AFT's FY21 total global sales of A$113M, it's clear that the company is very early on its journey. We think a large global TAM is a critical element of success for AFT because it gives a long growth runway for the company to compound its future earnings and returns, should AFT be able to drive penetration in those new markets.

What's also important to us is whereabout AFT is at now in terms of its investment in exploiting that very large TAM. The answer seems clear – a substantial chunk of heavy lifting has been done – see Figure 10 below.

Figure 10: Maxigesic commercialisation progress as of 19 October 2021

	Maxigesic tablets	Maxigesic IV
	Number of countries	
Licensed	100+	100+
Registered	51	27
Sold in	45	5

Source: Company, Pitt Street Research

In FY22 and beyond, we expect AFT to continue scale its licensing and registration of new dose forms across the other countries, which should further enlarge the size of its current market opportunity set.

AFT's continued success in obtaining regulatory approvals for Maxigesic IV in various countries paves the foundation for future growth as well as de-risks its investment case, in our view. Further, it's worth highlighting the global licensing/distribution relationships that AFT have recently established (Figure 11), which we expect to drive international sales in the near/medium term.

Figure 11: Maxigesic agreements 2021

Countries/Regions	Licensees/Distributors	Expected launch year
Maxigesic IV		
US	Hikma Pharmaceuticals	
Greece	Vianex	
Spain, Finland, Norway, Denmark, Sweden, Iceland, Portugal, the Netherlands	Aguettant	
Poland	Mercarpharm	
South Korea	Kyongbo Pharmaceutical Co	Early 2022
Caribbean, Central and Latin America	Pharma Bavaria	Late 2021
Maxigesic tablet		
Chile, Peru	Galenicum Vitae	2022
Poland	Mercarpharm	

Source: Company, Pitt Street Research

We expect the US market to be a key growth driver over the medium term

DelveInsight estimated the number of surgical procedures performed in the US for 2020 was around 50 million, with 80% of the procedures requiring post-operating pain management. If we assume that the average cost of a dose of intravenous analgesic is US$30[4,5,6], we can derive that the size of the US post-operative pain management market was US$1.2B in 2020. Again, we note that our estimates are for illustration purpose only and therefore don't represent definitive market size estimates. We have calculated a revenue matrix based on variations of our bottom-up inputs (Figure 12). As shown, the opportunity is material and narrowed from the wider global analgesic market. We believe this provides a clearer outlook of the market prize for AFT's Maxigesic IV.

Figure 11 shows that AFT has recently secured Hikma Pharmaceuticals as their licensee/distributor. Given that Hikma has a strong and respected US hospital market presence and is also the third largest US supplier of generic injectable medicines, we expect them to help AFT to drive the take up of Maxigesic IV in this market, if and when AFT obtains the required regulatory approvals. If AFT can replicate what it did in Australia/New Zealand there, the upside potential to its expected sales, earnings and cashflows will be significant, in our view.

We will now turn to the value proposition of the Maxigesic family of medicine, which we think will likely determine their penetration in various markets.

Figure 12: Bottom-up sales matrix for US post-operative pain management market

		Avg cost per dose of IV analgesic ($US)				
		20	25	30	35	40
Number of surgeries requiring post-operating pain mgmt (mn)	30	600	750	900	1050	1200
	35	700	875	1050	1225	1400
	40	800	1000	1200	1400	1600
	45	900	1125	1350	1575	1800
	50	1000	1250	1500	1750	2000

Source: Pitt Street Research estimates, DelveInsight, Allegheny County Medical Society

Maxigesic's value proposition

We believe Maxigesic products are differentiated and more superior versus traditional analgesics

As mentioned earlier, Maxigesic is a repurposed drug that combines two popular OTC analgesics, namely paracetamol and ibuprofen, into a unique patented formulation. More specifically, it contains a combination of 500mg paracetamol and 150mg ibuprofen, the result of which yields a synergistic effect that contributes to fast, effective pain relief without the use of opioids.

Shortly after its success in commercialising the oral/tablet dosage form of Maxigesic, AFT saw a lucrative opportunity in the post-operative pain management space and as such, quickly innovated and collaborated with Hyloris Pharmaceuticals (EBR: HYL) to develop a line extension called Maxigesic IV, which is a unique combination of 1000mg paracetamol and 300mg ibuprofen solution that can be injected into patients whilst they're still unconscious right after surgical procedures.

In our view, Maxigesic has a sustainable competitive advantage over opioid-based analgesics as well as some non-opioid analgesics.

[4] Source: A potential spin on pain control: A review of IV acetaminophen, *Allegheny County Medical Society*, 25 January 2021.
[5] Source: Acetaminophen. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL, 2 November 2020.
[6] We have used the average cost of a dose of intravenous acetaminophen as a proxy for estimating the pricing component of the market size equation.

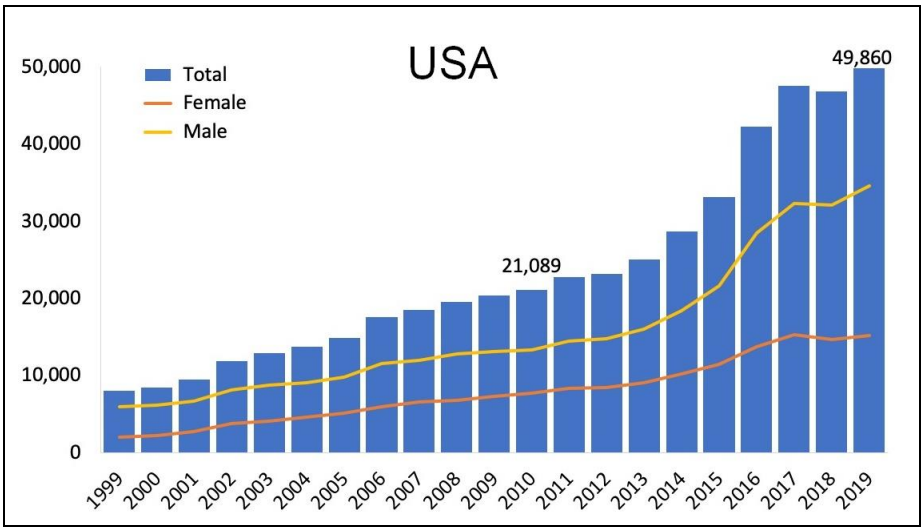
No side effects associated with opioid analgesics

As touched on earlier, opioids are medicines derived from opium compounds such as codeine, oxycodone and morphine. While they are primarily used for pain relief, opioids carry with them many side effects that include euphoria, itching, nausea and vomiting. Euphoria is likely to attract increased use, which often result in addiction. In turn, addiction could lead to overdose which may result in death.[7] Also, it's worth noting that extended use of opioids can cause tolerance and physical dependence.[8] Tolerance means higher doses are needed to obtain the same effect, whilst physical dependence means that cessation of the drug can result in troublesome withdrawal symptoms.

Globally, 69,000 people pass away due to opioid overdose every year, with 15 million people having an opioid addiction.[9] Figure 13 shows annual overdose deaths from all opioid drugs including opioid analgesics in US.

According to DelveInsight, opioids is one of the main pain-relieving analgesics used in the post-operative pain market, with the others being NSAIDs and anesthetics. Herein provides an opportunity for AFT as its Maxigesic IV drug is non-opioid and hence, mitigates the risks and side effects associated with opioid analgesics. Coupled with its strong effectiveness for pain management (see section below), we believe Maxigesic IV has the potential to displace opioid analgesics in the large global post-operative pain market.

Figure 13: National Drug Overdose Deaths Involving Any Opioid in US, 1999-2019



Source: Overdose Death Rates, by National Institute on Drug Abuse. Wikipedia.

More effective versus some non-opioid analgesics

NSAID such as ibuprofen acts as an alternative analgesic for post-operative pain relief. According to recent research[10] published by the Canadian Medical Association Journal, ibuprofen not only offers better pain management but also fewer side effects when compared to codeine (an opioid) after surgery[11]. And because ibuprofen is non-opioid, it therefore mitigates the addiction risk

[7] FDA requires strong warnings for opioid analgesics, prescription opioid cough products, and benzodiazepine labeling related to serious risks and death from combined use. *FDA*. 31 August 2016.
[8] Drug Facts: Prescription Opioids. *NIDA*. June 2019.
[9] Parthvi R, Agrawal A, Khanijo S, Tsegaye A, Talwar A (May–June 2019). Acute Opiate Overdose: An Update on Management Strategies in Emergency Department and Critical Care Unit. *American Journal of Therapeutics*. 26 (3): e380–e387.
[10] Choi M, Wang L, Coroneos CJ, Voineskos SH, Paul J. Managing postoperative pain in adult outpatients: a systematic review and meta-analysis comparing codeine with NSAIDs, *Canadian Medical Association Journal*, 14 June 2021; 193:E895-905.
[11] Source: See Note 10. Quoting: "We found high-quality evidence that outpatient postoperative adults taking NSAIDs reported less pain at 6 and 12 hours than those taking codeine in a meta-analysis of RCTs." RCT stands for randomised control trials.

associated with opioids. Prima facie, it appears that ibuprofen is a better and superior solution versus an opioid, which is codeine in this case.

By undertaking further research, we note that certain combination analgesic products such as paracetamol/ibuprofen can drive a further uplift in potency than the individual ingredients.[12,13] This concept had been further explored and clinically tested by AFT, which then resulted in the advent of Maxigesic. To reiterate, AFT's clinical trials had proven that Maxigesic yielded a beneficial synergistic effect which led to more effective pain relief to either paracetamol or ibuprofen alone. Its intravenous form, Maxigesic IV, had also been clinically tested which demonstrated that it was well-tolerated and had a faster onset of action and offered higher pain relief versus ibuprofen IV or paracetamol IV alone in the same doses.[14] More importantly, its formulation doesn't involve the use of opioids. In our view, the presence of these two attributes, being drug synergy and zero opioid use, offers Maxigesic a sustainable competitive advantage over both opioid-based analgesics as well as some non-opioid analgesics such as ibuprofen. As such, we believe Maxigesic has a strong value proposition, which in our view, could potentially allow it to disrupt the opioid and NSAID segments of the pain management market. Its initial success in the Australia and New Zealand markets reflect a proven value proposition, which we expect to underpin its commercial uptake in the international markets.

Skin treatment

Pascomer could potentially drive AFT's next leg of growth

Within AFT's strong product pipeline, we see Pascomer as having the highest likelihood for delivering the next set of growth cycle for the company.

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. And 75% of TSC patients tend to develop FA, which often impairs patients' facial appearance and reduces their quality of life.[15] As per management findings, this disease affects around 30,000 patients in the US and 50,000 patients in Europe[16]. Clearly, the opportunity is substantial.

Currently, AFT is in the process of undertaking a multi-centre global clinical trial for Pascomer, with the goal to ascertain the optimal dose at which the drug demonstrates biological activity with minimal side effects. With the gradual reopening of international borders, we expect AFT to finalise its trial study over the near future, the successful outcome of which should likely see AFT registering the product and then rolling it out to its initial markets, being the US and Europe. In turn, this should drive a material uplift in AFT's sales and cashflows over the medium term.

More significantly, AFT also executed two licensing agreements for Pascomer: 1) Timber Pharmaceuticals for North America, and 2) Desitin Arzneimittel GmbH for Europe. We are encouraged by these arrangements because they show interest and confidence from specialist pharmaceutical companies at AFT's Pascomer product.

[12] Bailey E, Worthington HV, van Wijk A, Yates JM, Coulthard P, Afzal Z. Ibuprofen and/or paracetamol (acetaminophen) for pain relief after surgical removal of lower wisdom teeth. *Cochrane Database Syst Rev* (12): CD004624. December 2013.
[13] Moore PA, Hersh EV. Combining ibuprofen and acetaminophen for acute pain management after third-molar extractions: translating clinical research to dental practice. *J Am Dent Assoc.* 144 (8): 898–908. August 2013.
[14] Source: AFT. Results from a randomised, double-blinded, placebo-controlled Phase 3 trial in 276 patients after bunion surgery.
[15] Hatano, T., Ohno, Y., Imai, Y. et al. Improved health-related quality of life in patients treated with topical sirolimus for facial angiofibroma associated with tuberous sclerosis complex. *Orphanet J Rare Dis* 15, 133 (2020).
[16] Tuberous Sclerosis Alliance: https://www.tsalliance.org/

New product launch and development

Apart from Maxigesic and Pascomer, AFT has also got plenty of other products in their pipeline that could potentially propel its future growth. As mentioned earlier, AFT's founder-led management team fosters an innovative culture in the workplace, which results in the continued development of its portfolio of repurposed medicines.

Crystawash Extend to capitalise on a structural shift to hand sanitisation

Hand sanitisation has gained increased popularity during COVID. As we push through COVID, we think the elevated demand for hand sanitisation will likely persist as COVID has arguably set a new and heightened standard of personal hygiene. AFT was early to recognise this trend and as such, developed a product called Crystawash Extend to accommodate the increased demand from consumers. Unlike the traditional alcohol-based sanitisers which often requires multiple uses and may cause skin inflammation, Crystawash Extend provides protection against multiple infected surfaces over a 24-hour period. Its efficacy has been validated by independent tests.[17,18,19] Hence, we believe Crystawash Extend has a strong product proposition which should help drive its international sales over the short to medium term.

NasoSURF – The big leap in drug delivery

Over the past years, AFT has been investing in developing NasoSURF, which is a hand-held nebuliser that aims for the intranasal delivery of medication. This device, when and if developed, could potentially receive strong interest from the medical community worldwide due to it being a lesser invasive form of drug delivery when compared to an injection. Management expects clinical studies of the first medicinal dose form to commence in 2021.

Figure 14: Crystawash Extend (left), NasoSURF (right)

Source: Company

[17] AFT Pharmaceuticals/AsureQuality Laboratory Services, New Zealand microbiological effectiveness study evaluating residual killing activity against transient microbial skin flora on synthetic skin (test organisms: S.Aureus NZRM 147/ATCC 6538 and E.Coli NZRM 2577/ATCC 8739).

[18] Time Kill Test conducted by Eurofins BioPharma Product Testing, Australia; Protocol: TMD-110, EN 13727; Test organisms: S.Aureus ATCC 6538, E.Coli NCTC 10538, P.aeruginosa ATCC 15442, and E. hirae ATCC 10541.

[19] Virucidal Test by Carrier Method conducted by Eurofins BioPharma Product Testing, Australia; Protocol: TMCV 006, ASTM E1053; Test organisms: Murine hepatitis virus (MHV1) ATCC/VR-261.

Financial performance and growth forecasts

Sales revenue

We have modelled the expected sales and royalties for AFT's two lead assets, namely Maxigesic and Pascomer. Within Maxigesic, we expect sales to accrue to the group from both tablet and intravenous forms.

Asset #1: Maxigesic Tablet

- We dissect future sales into: 1) sales from existing countries, and 2) sales from new countries. We model existing sales to grow by 5-6% pa as we expect AFT to drive penetration in their newly launched markets. On new sales, we derive this based on our estimated number of new countries in which AFT will register and sell its product in, and avg sales per country. We also apply a probability factor[20] to account for AFT's success in getting product registrations for the new countries. See Figure 15, Figure 16 and Figure 17 for our expected risk-adjusted sales profile.

Asset #2: Maxigesic IV

- We apply a market share approach to derive expected sales. We assume a global TAM of US$2.1B (Figure 6) and a 30-40% matured market share, driven by Maxigesic IV's superior value proposition over opioid analgesics as well as some non-opioid based analgesics (refer to previous section for more detail). Similar to its tablet form, AFT will need to register Maxigesic IV in every new country before being allowed to distribute them. As such, we de-risk our expected sales using the same probability factor. Further, we factor in the milestone payments that AFT may receive from Hikma Pharmaceuticals over the coming years. Figure 18 shows our risk-adjusted sales modelling up to FY24e, after which we expect sales to sequentially ramp up, ultimately reaching annual peak sales of c.NZ$700M by FY27e.

Asset #3: Pascomer

- A market share approach is used to forecast sales. We model only the US and EU markets as AFT's primary commercialisation markets. According to management, the size of the US market for facial angiofibromas could be worth US$300M, whilst the market potential for EU could be around US$200M. In aggregate, we derive a TAM of US$500M.
- A 50-60% matured market share has been assumed, owing to the nature of Pascomer being an orphan drug that faces limited competition.
- Given AFT is close to completing a multi-centre global Phase II/III clinical trial for Pascomer, we ascribe 10-12% for royalty rate and 50-60% chance of reaching market.
- See Figure 19 for our expected royalty-based sales profile for Pascomer.

Earnings profile

As AFT grows its international sales, we expect costs as a proportion of total sales to reduce due to scale efficiency and operational leverage.

We assume AFT will continue invest in R&D at 10% of sales pa, reflecting its historical avg rate (Figure 5).

Near term, we expect AFT to achieve NZ$133.9M in sales for FY22e, cutting through to NZ$20.2M in operating profit at a margin of 15.1% (Figure 20).

[20] We factor in an 80-90% probability of success as AFT had clinically proven its Maxigesic tablet product and already obtained registrations in >50 countries.

Figure 15: Maxigesic tablet countries sold

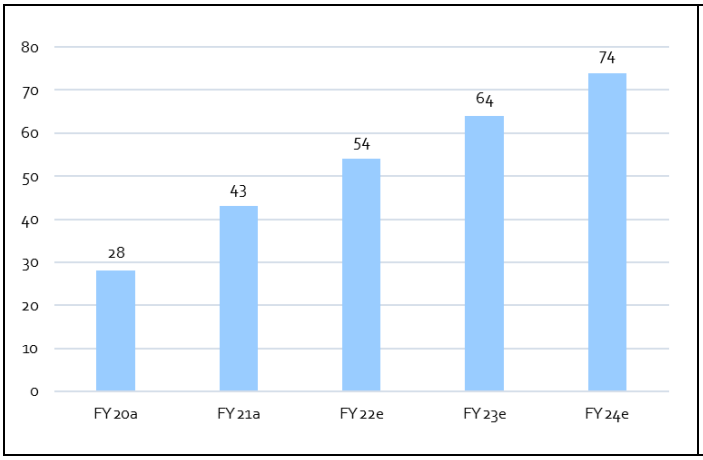
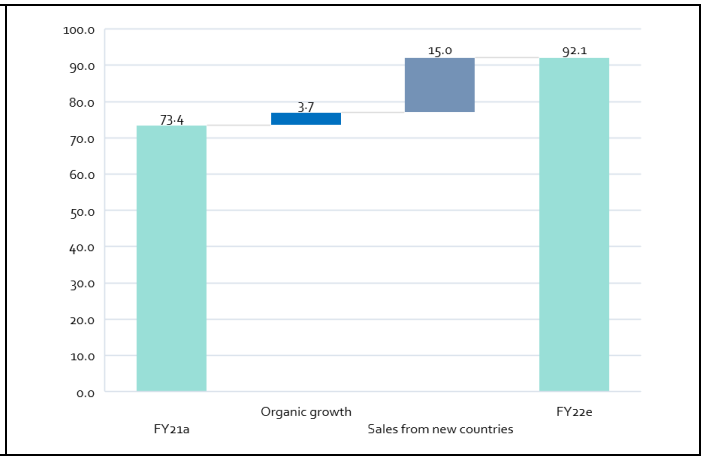


Figure 16: Maxigesic tablet FY22e sales profile (NZD m)



Source: Company, Pitt Street Research

Figure 17: Maxigesic tablet sales profile (NZD m)

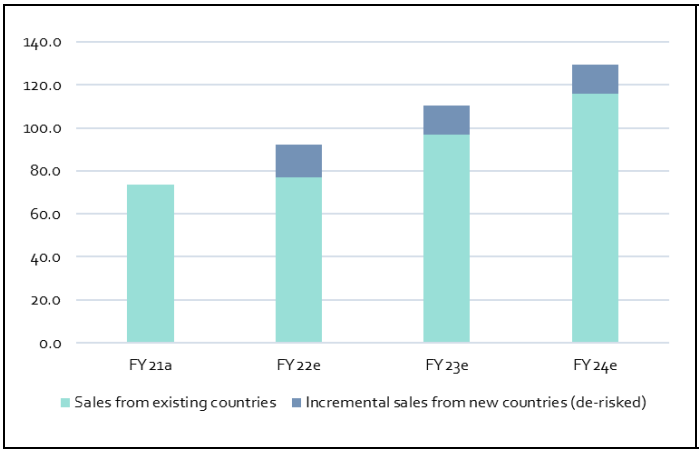
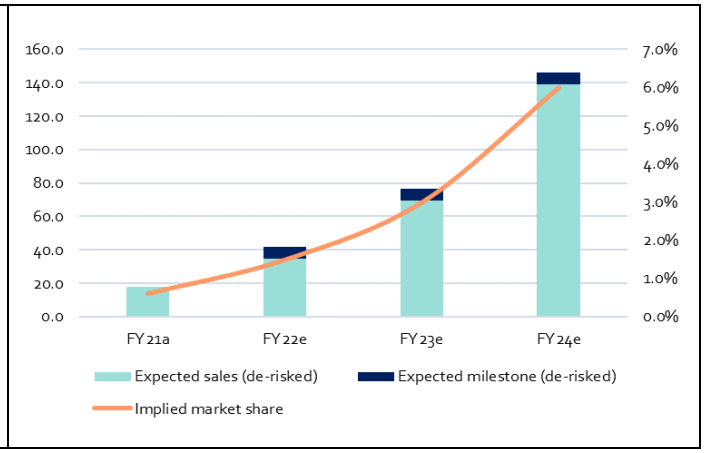


Figure 18: Maxigesic IV sales profile (NZD m)



Source: Company, Pitt Street Research

Figure 19: Pascomer royalty-based sales profile (NZD m)

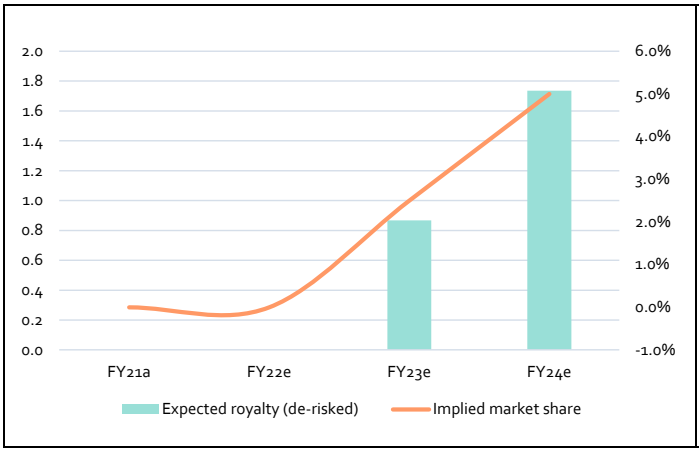
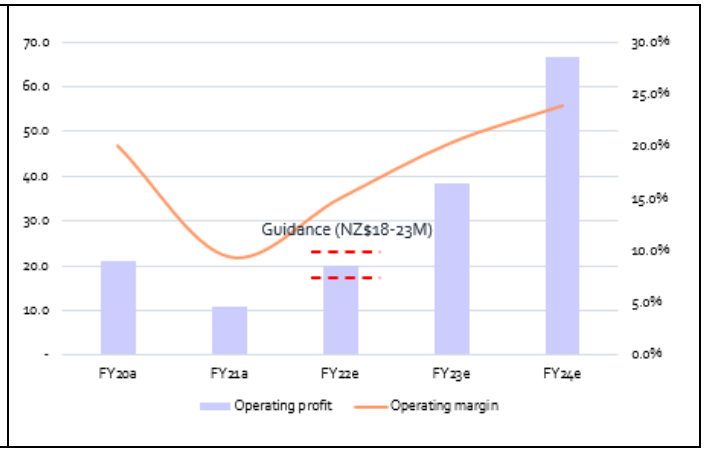


Figure 20: AFT earnings profile (NZD m)



Source: Company, Pitt Street Research

Valuation

We use a DCF model to frame our valuation for AFT. Our baseline valuation is at NZ$6.09ps, whilst our bull case arrives at NZ$9.29ps.

To summarise, our valuation is solely driven by expected sales, earnings and cashflows from AFT's three lead assets, being Maxigesic tablet, Maxigesic IV and Pascomer. Our valuation incorporates AFT's global rollout strategy and reflects the company's ability to win share in both existing and new markets.

We note that AFT is also commercialising various other products, which we expect to drive upside risks to our forecasts and valuation.

Our DCF assumes a 10.0%[21] discount rate and a 11-year[22] forecast horizon.

Figure 21: DCF summary

Valuation	
Present value of FCF	672.8
Present value of Terminal FCF	-
Enterprise Value (NZ$M)	**672.8**
Net debt (cash)	35.2
Equity value (NZ$)	**637.6**
Share outstanding	104.7
Implied price (NZ$)	**6.09**
Current price (NZ$)	4.83
Upside (%)	*26.1%*

Valuation	
Present value of FCF	1,007.1
Present value of Terminal FCF	-
Enterprise Value (NZ$M)	**1,007.1**
Net debt (cash)	35.2
Equity value (NZ$)	**971.9**
Share outstanding	104.7
Implied price (NZ$)	**9.29**
Current price (NZ$)	4.83
Upside (%)	*92.3%*

Source: Pitt Street Research

Catalysts

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

- Better than expected global uptake of the Maxigesic family of products;
- Obtaining regulatory approvals and registrations for new countries; and
- Positive results from clinical studies for Pascomer.

[21] For a relevant discount rate, we use varying WACCs depending on the risk for Life Science companies. We start with an RFR of the Australian ten-year bond rate (1.7%) and an ungeared beta of 1.1 but use a variable MRP of 7.5%-11.5% (7.5% for 'medium risk' companies, 9.5% for 'high risk' companies and 11.5% for 'speculative' companies). Ordinarily we regard Life Science companies with existing businesses, or who have enough capital to reach the market with their products, as 'Medium' risk. Companies that have small revenue streams from marketed products but that are still potentially in need of capital are 'High' risk. Everything else is 'Speculative'. We have used a 'Medium' risk rating for AFT Pharmaceuticals given its track record of bringing new products to market and is generating profits.

[22] We assume 7, 10 and 11 years of commercial exclusivity for AFT's Maxigesic tablet, Pascomer and Maxigesic IV respectively.

Risks

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

- **Uptake risk**: There is a risk that AFT may not 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 materialises, 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 commercialisation timeline for the product.
- **Competition risk**: There is the "what if" scenario where new and/or existing competitors coming up with a superior and cheaper product that seeks to address the same market opportunity set as AFT. If this risk materialises, 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 in that market.
- **Currency risk**: AFT buys goods and services from offshore suppliers. This exposes AFT to foreign currency risk.

Appendix I – Glossary

Analgesic – A drug that acts to relief pain, also widely known as a painkiller.

Facial angiofibromas – Hamartomatous growths that are closely related to tuberous sclerosis complex.

NSAIDs – Non-steroidal anti-inflammatory drugs which include aspirin, ibuprofen and naproxen.

Opioids – Medicines derived from opium compounds such as codeine, oxycodone and morphine. Opioids affect gastrointestinal tract and nervous system.

Orphan drug – A drug that is developed specifically to treat a rare medical condition.

OTC – Over-the-counter medicines can be purchased directly by consumers without a prescription.

Tuberous Sclerosis Complex – A rare genetic disorder that causes benign tumours to grow in various parts of the body.

Appendix II – Capital structure

As of 23 June 2021, AFT had 104.7 million in fully ordinary shares.

Appendix III – Leadership team

- **CEO, Executive Director and Co-Founder Dr Hartley Atkinson** has a Masters of Pharmaceutical Chemistry with Distinction (1983) and a Doctorate in Pharmacology from Otago University (1989). He published 17 research papers and two book chapters prior to entering the industry. Before establishing AFT Pharmaceuticals, Hartley worked for eight years in multi-national pharmaceutical companies including Medical Director and Sales and Marketing Director positions.
- **Chief of Staff, Executive Director and Co-Founder Marree Atkinson** has been involved in all aspects of AFT's business since its establishment in 1997, including roles in sales, regulatory affairs, customer services and logistics. Marree's role as Chief of Staff sees her involved in the day-today running of AFT's head office including managing staffing requirements and special projects involving AFT's head and affiliate offices. Marree is a registered nurse previously practising at Waikato Hospital.
- **CFO Malcolm Tubby** is a qualified Chartered Accountant in the United Kingdom and New Zealand with a wealth of senior corporate governance expertise in the commerce sector, including roles in significant public companies as Chief Financial Officer. He has experience in senior positions in public and private companies in pharmaceuticals, beverages, insurance and aged care facilities in Australia and New Zealand. Malcolm has also been involved with the AFT board since our foundation in 1998.
- **Head of Drug Development Ioana Stanescu** has overall responsibility for AFT's R&D. She has over 20 years' experience in the pharmaceutical industry, including positions as VP QA & Regulatory Affairs and Head of Vaccine Business Area at FIT Biotech Ltd, and a WHO adviser within Central and Eastern Europe. She has also coordinated several European FP6 and FP7 funded research grants and was selected as an Expert by the European Health Committee – Council of Europe to participate in a research study in 1999.

- **Chairman David Flacks** has a number of governance roles and has been chair of AFT Pharmaceuticals since the IPO in 2015. He is chair of the Regulatory Governance Committee of the NZX, chair of the Suncorp NZ group of companies and Harmoney Corp. He is also a director of a number of environmentally focused pro bono organisations. He is a former chair of the NZX Markets Disciplinary Tribunal and a former member of the Takeovers Panel. He is also a director of boutique corporate law firm Flacks & Wong. David was for many years a senior corporate partner at Bell Gully and was general counsel and company secretary of Carter Holt Harvey during the 1990's. He is a law graduate from Cambridge University.
- **Independent Director Doug Wilson** was a New Zealand physician and academic. He joined a major International pharmaceutical company, Boehringer Ingelheim, working in their US subsidiary, becoming their Head of Medical Research and Regulatory Affairs, the interface with FDA, playing a major role in steering 10 drugs through the FDA to the US and global markets. He moved to Head Office in Germany, being responsible for those same functions for worldwide drug development. He chaired the company's International Medical Committee overseeing the medical aspects of all drugs in development globally, and their Internal Labelling Committee for the drugs on the worldwide market. He was the medical parent of Spiriva, a drug for Chronic Obstructive Pulmonary Disease (COPD), one of the major global killers. The drug last year sold $5 billion. He now consults internationally on new drugs in development, and for pharmaceutical companies.
- **Independent Director Jon Lamb** has led the strategic planning, marketing and restructuring of various companies throughout his career. He has held various roles at Beecham (a multinational pharmaceutical company that would later merge with a predecessor company to GlaxoSmithKline) including CEO in New Zealand and Marketing Manager in both Australia and South Africa. He has also held roles as CEO of Nylex in New Zealand, Managing Director within the Rural Division of Fletcher Challenge, Director of Southland Frozen Meats and Marketing Director of the New Zealand Kiwifruit Marketing Board (where he was responsible for creating the Zespri brand of kiwifruit, and restructuring Zespri into a retail focussed operation). Jon has been involved with AFT since 2004, firstly as a consultant, and then in his current capacity as a director.
- **Independent Director Anita Baldauf** joins AFT with a broad and international experience in FMCG and Corporate Finance. Her 22 year career at Nestlé and L'Oréal (Laboratoires innéov), mostly as CFO in multiple developed and developing countries, gave her a rich expertise in finance and investor relation, compliance and governance, international business as well as people development, and value based leadership. Anita is impassioned about driving impact, particularly in the area of Wellbeing and mental health. She is an EHF Fellow, where she is advising and supporting New Zealand and international start-ups and impact ventures as they navigate through the challenges of exponential change, rapid growth, and their aim for impact and sustainability.
- **Independent Non-Executive Director** Dr. Ted Witek served Boehringer Ingelheim Pharmaceuticals for nearly 25 years where he held various pharmacology and clinical research positions, including Director of Respiratory and Immunology Clinical Research leading to his roles as President and CEO of Boehringer Ingelheim's Canadian and Portuguese operations. He led the Global Operating Team for Spiriva serving as Co-

Chair of the Global Alliance with Pfizer. Dr. Witek holds a Doctor of Public Health from Columbia University and a Master of Public Health from Yale University and an MBA from Henley Management College in the UK.

Appendix IV – Analysts' qualifications

Cheng Ge, lead analyst on this report, is an equity research analyst at Pitt Street Research.

- Cheng obtained a B.Com in Finance and LL.B from University of New South Wales, in 2013. He also completed all three levels of the CFA Program.
- Before joining Pitt Street Research, he worked for several financial services firms in Sydney, where his focus was on financial advice.
- He joined Pitt Street Research in January 2020.

Stuart Roberts has been covering the Life Sciences sector 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 specialty 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 in 2015 and 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 Science 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 Science companies.

AFT Pharmaceuticals Ltd

Profit & Loss (NZ$m)	FY20a	FY21a	FY22e	FY23e	FY24e
Sales Revenue	**105.6**	**113.1**	**133.9**	**187.8**	**277.3**
EBITDA	**22.3**	**11.8**	**21.5**	**40.1**	**69.1**
D&A	(1.1)	(1.1)	(1.4)	(1.9)	(2.8)
EBIT	**21.2**	**10.7**	**20.2**	**38.2**	**66.3**
Net Interest	(8.3)	(2.8)	(3.2)	(2.8)	(2.7)
Profit before tax (before exceptionals)	**12.9**	**7.9**	**16.9**	**35.5**	**63.6**
Tax expense	(0.2)	(0.1)	-	(11.5)	(19.9)
Abnormals + Minorities	-	-	-	-	-
NPAT	**12.7**	**7.8**	**16.9**	**24.0**	**43.7**

Cash Flow (NZ$m)	FY20a	FY21a	FY22e	FY23e	FY24e
Profit after tax	12.7	7.8	16.9	24.0	43.7
D&A	1.1	1.1	1.4	1.9	2.8
Change in working capital	1.0	(11.6)	2.5	(6.9)	(11.4)
Other operating activities	0.1	3.5	-	-	-
Operating cashflow	**14.9**	**0.8**	**20.7**	**19.0**	**35.1**
Capex	(6.6)	(6.2)	(6.4)	(6.5)	(6.5)
Other investing activities	-	-	-	-	-
Investing cashflow	**(6.6)**	**(6.2)**	**(6.4)**	**(6.5)**	**(6.5)**
Dividends	(0.6)	(0.2)	-	-	-
Equity raised (repurchased)	0.0	11.7	-	-	-
Debt drawdown (repaid)	(2.1)	(6.5)	(5.2)	-	-
Other financing activities	(6.4)	(2.5)	-	-	-
Net change in cash	(0.8)	(3.0)	9.1	12.5	28.6
Cash at End Period	6.1	3.2	12.3	24.9	53.4
Net Debt (Cash)	37.1	35.2	20.9	8.3	(20.2)

Balance Sheet (NZ$m)	FY20a	FY21a	FY22e	FY23e	FY24e
Cash	6.1	3.2	12.3	24.9	53.4
Total Assets	87.1	105.1	118.7	153.0	216.5
Total Debt	43.2	38.4	33.2	33.2	33.2
Total Liabilities	69.8	68.5	65.2	75.5	95.2
Shareholders' Funds	17.3	36.6	53.5	77.5	121.2

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