

AFT Pharmaceuticals

Big win with Maxigesic Rapid's FDA nod

Regulatory update

Pharma and biotech

AFT Pharmaceuticals (AFT) has [announced](#) it has received FDA approval for Maxigesic Rapid tablets, a quick-release version of its flagship Maxigesic product line. Notably, this marks the first regulatory win for AFT in the US (the world's largest analgesic market), valued at c US\$7bn. While AFT awaits Maxigesic IV's clearance in the US, we expect this approval to help it build initial commercial traction in this high-margin market. The Rapid tablets, a patented combination of paracetamol (325mg) and ibuprofen (97.5mg), has been authorised for the treatment of mild-to-moderate acute pain. Negotiations with potential distribution partners are ongoing, with plans to release other dose versions in the future. The market has reacted positively to the news, with shares trading up by 10% at close of business.

Year end	Revenue (NZ\$m)	PBT* (NZ\$m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
03/21	113.1	8.2	7.1	0.00	52.4	N/A
03/22	130.3	18.9	19.2	0.00	19.4	N/A
03/23e	152.2	17.6	13.4	2.57	27.8	0.7
03/24e	189.7	31.3	21.7	4.22	17.1	1.1

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

Maxigesic, AFT's flagship product, is a double-action analgesic (patented combination of paracetamol and ibuprofen). Maxigesic Rapid uses the same combination, at 65% strength of the original tablet form, based on the company's patented rapid release technology. We note that the patent for the dose ratio and rapid-release technology will expire in 2025 and 2039, respectively.

This approval will mark the first entry for AFT in the lucrative US market following the delay in receiving approval for the IV formulation due to certain packaging-related concerns (Hikma is the licensing partner for Maxigesic IV in the US). US is the largest analgesics market globally, pegged at [US\\$7.2bn](#), and estimated to grow at a CAGR of 5.8% during 2023–2027. We believe this approval will help AFT build an initial commercial presence in the US, with user feedback likely to influence approval and launch of other dose formats, including the IV version. This also follows recent wins such as the approval of Maxigesic oral liquid (targeted at the paediatric population) in an additional 12 European countries and a distribution agreement for Maxigesic IV in nine Eastern European countries.

Maxigesic is the key commercial driver for AFT with plans for international expansion (73 countries by FY24) and the launch of new variants, such as the Maxigesic cold and flu/sinus and pain treatment kit in Australia. The anticipated US approval of Maxigesic IV is a key catalyst for the company in CY23, in our opinion. The R&D pipeline remains robust with multiple projects under development, including Maxigesic dry stick sachets (flavoured granules), the NanoSURF nasal nebuliser (targeting FDA submission by the end of CY24), Pascomer's pilot study in port wine stains and an early-stage development programme for topical treatment of strawberry birthmarks. We expect development to support top-line growth in the near to medium term.

2 March 2023

Price **NZ\$3.72**

Market cap **NZ\$390m**

NSS\$0.62/US\$

Net cash (NZ\$m) at 30 September 2022 28.9

Shares in issue 104.9m

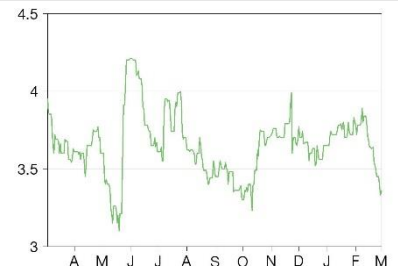
Free float 26.2%

Code AFT

Primary exchange NZX

Secondary exchange ASX

Share price performance



Business description

AFT Pharmaceuticals is a specialty pharmaceutical company that operates primarily in Australasia but has product distribution agreements across the globe. Its product portfolio includes prescription and over-the-counter drugs to treat a range of conditions as well as a proprietary nebuliser.

Analysts

Soo Romanoff +44 (0)20 3077 5700

Jyoti Prakash, CFA +44 (0)20 3077 5700

Nidhi Singh +44 (0)20 3077 5700

healthcare@edisongroup.com

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