

AFT Pharmaceuticals

Maxigesic IV closer to FDA approval

AFT Pharmaceuticals has announced that the US FDA has allocated a Prescription Drug User Fee Act (PDUFA) date for Maxigesic IV, an intravenous form of its flagship pain relief medicine. The PDUFA date is expected to be the last step in the FDA review process and has been set for 17 October 2023. It follows submission of additional requested data in April 2023 in response to the complete response letter (CRL) received from the FDA in July 2022 (related to queries about certain extractable and leachable compounds present in Maxigesic IV's packaging) following the 2021 New Drug Application. The IV formulation is registered in 43 countries and has been launched in more than 19 (including the key markets of Germany, France and Italy), but the US is expected to be a key high-margin market. We note that Maxigesic IV was out-licensed to Hikma Pharmaceuticals in the US in 2021 for up to NZ\$18.8m in proceeds.

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	47.3	N/A
03/22	130.3	18.9	19.2	0.00	17.5	N/A
03/23e	152.2	17.6	13.4	2.57	25.1	0.8
03/24e	189.7	31.3	21.7	4.22	15.5	1.3

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). The IV version uses a double-strength formulation of the oral version (1000mg paracetamol and 300mg ibuprofen) and targets hospitals for the treatment of patients with post-operative pain. While AFT is self-commercialising Maxigesic IV in its domestic markets (Australia and New Zealand), commercialisation activities in other geographies have been out-licensed to regional partners. The IV formulation has been licensed in more than 100 countries, approved in 43 and launched in more than 19 countries including Australia, France, Germany, Italy, Indonesia and Korea.

As a reminder, AFT had received a CRL from the US FDA for its application for Maxigesic IV in <u>July 2022</u>, with observation related to the leachable compounds present in the packaging of the product (the glass vial in which the medicine is stored and the vial's stopper). In response, AFT, along with partner Hyloris Pharmaceuticals, initiated <u>additional studies</u> to address the FDA's queries, generating incremental data on extractable and leachable compounds from the packaging. AFT and Hyloris submitted their response in April 2023. Setting a PDUFA date means that the FDA believes the additional data and submission represent a complete response in relation to its outstanding queries on extractables and leachables in the product packaging.

We see the above development as a step towards potential FDA approval of the IV formulation in the US, the world's largest analgesic market valued at c US\$7bn. We note that in March 2023, AFT received its first regulatory win in the US with the approval of Maxigesic Rapid, a quick-release version of its core Maxigesic product. If approved, we estimate Maxigesic IV will be launched in the US in CY24.

Regulatory update

Pharma and biotech

2 May 2023

Price NZ\$3.36

Market cap NZ\$352m

NZ\$0.62/US\$

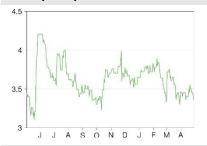
Net debt (NZ\$m) at 30 September 2022 28.9

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.

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