

# AFT Pharmaceuticals

## Maxigesic IV closer to FDA approval

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.

### Analysts

Soo Romanoff +44 (0)20 3077 5700

Nidhi Singh +44 (0)20 3077 5700

[healthcare@edisongroup.com](mailto:healthcare@edisongroup.com)

[Edison profile page](#)

**AFT Pharmaceuticals is a research client of Edison Investment Research Limited**

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 [July 2022](#), 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 [additional studies](#) 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.

---

## General disclaimer and copyright

This report has been commissioned by AFT Pharmaceuticals and prepared and issued by Edison, in consideration of a fee payable by AFT Pharmaceuticals. Edison Investment Research standard fees are £60,000 pa for the production and broad dissemination of a detailed note (Outlook) following by regular (typically quarterly) update notes. Fees are paid upfront in cash without recourse. Edison may seek additional fees for the provision of roadshows and related IR services for the client but does not get remunerated for any investment banking services. We never take payment in stock, options or warrants for any of our services.

**Accuracy of content:** All information used in the publication of this report has been compiled from publicly available sources that are believed to be reliable, however we do not guarantee the accuracy or completeness of this report and have not sought for this information to be independently verified. Opinions contained in this report represent those of the research department of Edison at the time of publication. Forward-looking information or statements in this report contain information that is based on assumptions, forecasts of future results, estimates of amounts not yet determinable, and therefore involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of their subject matter to be materially different from current expectations.

**Exclusion of Liability:** To the fullest extent allowed by law, Edison shall not be liable for any direct, indirect or consequential losses, loss of profits, damages, costs or expenses incurred or suffered by you arising out of or in connection with the access to, use of or reliance on any information contained on this note.

**No personalised advice:** The information that we provide should not be construed in any manner whatsoever as, personalised advice. Also, the information provided by us should not be construed by any subscriber or prospective subscriber as Edison's solicitation to effect, or attempt to effect, any transaction in a security. The securities described in the report may not be eligible for sale in all jurisdictions or to certain categories of investors.

**Investment in securities mentioned:** Edison has a restrictive policy relating to personal dealing and conflicts of interest. Edison Group does not conduct any investment business and, accordingly, does not itself hold any positions in the securities mentioned in this report. However, the respective directors, officers, employees and contractors of Edison may have a position in any or related securities mentioned in this report, subject to Edison's policies on personal dealing and conflicts of interest.

Copyright: Copyright 2023 Edison Investment Research Limited (Edison).

---

## Australia

Edison Investment Research Pty Ltd (Edison AU) is the Australian subsidiary of Edison. Edison AU is a Corporate Authorised Representative (1252501) of Crown Wealth Group Pty Ltd who holds an Australian Financial Services Licence (Number: 494274). This research is issued in Australia by Edison AU and any access to it, is intended only for "wholesale clients" within the meaning of the Corporations Act 2001 of Australia. Any advice given by Edison AU is general advice only and does not take into account your personal circumstances, needs or objectives. You should, before acting on this advice, consider the appropriateness of the advice, having regard to your objectives, financial situation and needs. If our advice relates to the acquisition, or possible acquisition, of a particular financial product you should read any relevant Product Disclosure Statement or like instrument.

---

## New Zealand

The research in this document is intended for New Zealand resident professional financial advisers or brokers (for use in their roles as financial advisers or brokers) and habitual investors who are "wholesale clients" for the purpose of the Financial Advisers Act 2008 (FAA) (as described in sections 5(c) (1)(a), (b) and (c) of the FAA). This is not a solicitation or inducement to buy, sell, subscribe, or underwrite any securities mentioned or in the topic of this document. For the purpose of the FAA, the content of this report is of a general nature, is intended as a source of general information only and is not intended to constitute a recommendation or opinion in relation to acquiring or disposing (including refraining from acquiring or disposing) of securities. The distribution of this document is not a "personalised service" and, to the extent that it contains any financial advice, is intended only as a "class service" provided by Edison within the meaning of the FAA (i.e. without taking into account the particular financial situation or goals of any person). As such, it should not be relied upon in making an investment decision.

---

## United Kingdom

This document is prepared and provided by Edison for information purposes only and should not be construed as an offer or solicitation for investment in any securities mentioned or in the topic of this document. A marketing communication under FCA Rules, this document has not been prepared in accordance with the legal requirements designed to promote the independence of investment research and is not subject to any prohibition on dealing ahead of the dissemination of investment research.

This Communication is being distributed in the United Kingdom and is directed only at (i) persons having professional experience in matters relating to investments, i.e. investment professionals within the meaning of Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "FPO") (ii) high net-worth companies, unincorporated associations or other bodies within the meaning of Article 49 of the FPO and (iii) persons to whom it is otherwise lawful to distribute it. The investment or investment activity to which this document relates is available only to such persons. It is not intended that this document be distributed or passed on, directly or indirectly, to any other class of persons and in any event and under no circumstances should persons of any other description rely on or act upon the contents of this document.

This Communication is being supplied to you solely for your information and may not be reproduced by, further distributed to or published in whole or in part by, any other person.

---

## United States

Edison relies upon the "publishers' exclusion" from the definition of investment adviser under Section 202(a)(11) of the Investment Advisers Act of 1940 and corresponding state securities laws. This report is a bona fide publication of general and regular circulation offering impersonal investment-related advice, not tailored to a specific investment portfolio or the needs of current and/or prospective subscribers. As such, Edison does not offer or provide personal advice and the research provided is for informational purposes only. No mention of a particular security in this report constitutes a recommendation to buy, sell or hold that or any security, or that any particular security, portfolio of securities, transaction or investment strategy is suitable for any specific person.

---