EDISON

AFT Pharmaceuticals

Regulatory update

Maxigesic IV hits a roadblock in the US

Pharma & biotech

In an unexpected development, AFT Pharmaceuticals (AFT) has announced that it has received a complete response letter (CRL) from the United States Food and Drug Agency (FDA) on its application for Maxigesic IV, an intravenous form of its flagship pain relief medicine. Crucially, the observation does not appear to be related to clinical data but involves leachable compounds present in the drug product, which can be addressed fairly quickly, in our opinion. Revised timelines for the data resubmission and commercialisation will be communicated shortly. As a reminder, Maxigesic IV is already launched in seven countries and was out-licensed to Hikma Pharmaceuticals in the US in April 2021 for up to $18.8m in total proceeds. We will reassess our valuation of AFT in light of this development but expect a slight delay in commercial launch.

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	N/A	N/A
03/22	130.3	18.9	19.2	0.00	N/A	N/A
03/23e	155.9	27.0	20.4	4.04	N/A	N/A
03/24e	194.2	43.5	30.0	5.94	N/A	N/A

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

The CRL on Maxigesic IV's application in the US comes as a surprise given that the formulation has already received approval in 39 countries and has been launched in seven countries including the key European market, Germany. The new drug application (NDA) was backed by positive data from two Phase III studies: a randomised, double-blind, placebo-controlled trial in 276 patients and an open-label, multi-centre, single-arm, multiple-dose safety study in 232 patients. Maxigesic IV had reported a faster onset of action and higher pain relief compared to ibuprofen IV or paracetamol IV alone in the same doses.

Partner Hyloris has communicated that the FDA has not highlighted any issues related to clinical data and the deficiency is restricted to the quality, more specifically to revise a risk assessment of the required leachable compound study. The revised timelines and commercial pathway will be communicated shortly. While AFT is self-commercialising Maxigesic IV in its domestic Australia and New Zealand markets, commercialisation activities in other geographies have been out-licensed to regional partners. In the US, Maxigesic IV was out-licensed to Hikma in April 2021 for up to $18.8m in upfront and milestone payments as well as royalties on sales (of which $3.6m was received in H122).

We estimate Maxigesic IV to comprise less than 5% of international sales (or 0.5% of group revenue), being a fairly recent launch. We had been cautious in our estimates for Maxigesic IV in the US, pending FDA approval, and we will revisit our estimates and valuation to factor in this development. Nearer term, with over 20 products expected to be launched in Australia in FY23, domestic markets (over 85% of sales, the rest from Asia) should continue to dominate. Upcoming results from the Pascomer Phase II study, if positive, could add upside.

6 July 2022

Price	**NZ$3.35**
Market cap	**NZ$351m**
	NZ$0.65/US$
Net debt (NZ$) at 31 March 2022	29.3m
Shares in issue	104.9m
Free float	26.8%
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. The company's product portfolio includes prescription and over-the-counter drugs to treat a range of conditions, and a proprietary nebuliser.

Analysts

Soo Romanoff +44 (0)20 3077 5700

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

healthcare@edisongroup.com

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Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
1185 Avenue of the Americas
3rd Floor, New York, NY 10036
United States of America

Sydney +61 (0)2 8249 8342
Level 4, Office 1205
95 Pitt Street, Sydney
NSW 2000, Australia