



*Working to improve your health*

1 July 2025

**June Quarter FY 2026 Investor Update**

## **Combogesic IV launches in Canada; R&D progress**

### **Q1 FY 26 HIGHLIGHTS**

- Maxigesic IV® (marketed as Combogesic IV®) launching in Canada this month and sales kick off for AFT Pharmaceuticals Canada as AFT builds out its presence in North America.
- US Maxigesic licensing agreement with Hikma Pharmaceuticals extended to maximise the commercial footprint of the medicine.
- Research and development program significant advances with:
  - o pre-Investigational New Drug application (pre-IND) for our antibiotic eyedrop already filed and IND to be filed this year with the US Food and Drug Administration (FDA)
  - o preparing to file a further pre-IND application for our Strawberry Birth Marks topical treatment this year
  - o preparing to file an IND for the novel iron injection around year end
  - o addition of a further project for an improved formulation
- An interview with AFT managing Director Hartley Atkinson is available from the following link <https://youtu.be/r3nxyp62Khg>

AFT Pharmaceuticals (NZX: AFT; ASX: AFP) is this month starting sales for AFT Pharmaceuticals Canada by launching its patented intravenous pain relief medicine, Maxigesic IV in Canada (marketed as Combogesic), building on the company's strategy to expand in selected international markets.

Combogesic IV combines 1000mg paracetamol and 300mg ibuprofen in a single injectable formulation for the treatment of mild to moderate pain. When used in combination with the tablet form of the medicine, it provides clinicians with a valuable alternative to opioids in both operative settings and in post-discharge care.

AFT Managing Director, Dr Hartley Atkinson, said: "We see strong potential for Combogesic IV in Canada. The country is seeking safer, non-opioid approaches to pain management, and our dual-formulation Combogesic patented platform offers clinicians precisely that—an effective alternative to reduce opioid use."

The launch comes as Canada continues to grapple with a severe opioid crisis. Since 2016, more than 49,000 opioid-related deaths have been reported, along with over 45,000 hospitalisations and 187,000 emergency department visits<sup>1</sup>. Canada's opioid-

---

<sup>1</sup> <https://www.canada.ca/en/health-canada/services/opioids/federal-actions/overview.html>

related mortality rate, 6.9 per 100,000 population, is second only to the United States globally<sup>2</sup>.

The 2017 Canadian Guideline for Opioid Therapy and Chronic Non-Cancer Pain recommends prioritising non-opioid pharmacotherapies, including NSAIDs<sup>3</sup>, to reduce reliance on opioids, which are associated with a 5.5% risk of addiction<sup>4</sup>. Canada's analgesics market is forecast to grow at a CAGR of 6.1% to US\$1.88 billion by 2030<sup>5</sup>.

AFT will commercialize Combogesic IV through its recently established Canadian business hub, led by experienced local pharmaceutical executive Sylvain Desjeans. The Canadian business, which will sell a number of AFT's own medicines and in-licensed products, has been established as part of AFT's strategy to extend its footprint to territories that offer similar trading characteristics as its core Australasian business.

Further launches of OTC products are planned during this FY 26 financial year followed by a significant pipeline of in-licensed products, products developed by AFT and AFT Pharm Sinoject. It has set up similar operations in Singapore, Hong Kong, South Africa, the US, Europe and the UK.

### **US MAXIGESIC PARTNERSHIP EXTENDED**

The expansion into Canada builds on a broader strategy in North America. In late May AFT announced it had extended its US Maxigesic licensing agreement with Hikma Pharmaceuticals. The new agreement is aimed to maximise the commercial and patient care benefits that come with following the intravenous form of the pain relief medicine (marketed as Combogesic IV in the US) in postoperative care with the tablet form of the medicine (Combogesic Rapid).

The agreement will see Hikma take over all channels for Combogesic Rapid in the US — apart from the license granted to Alexso for certain specific market categories — allowing both forms of AFT's patented medicines to be marketed across the entire US market. The US is the world's largest market for pain relief<sup>6</sup>.

AFT and Hikma have also agreed to a restructure of the profit share arrangements for Combogesic IV. The agreement amends the previous profit share which featured a fixed specified profit amount before sharing commenced, to now being a regular quarterly profit share payment. AFT will be more involved in the sales and marketing planning for Combogesic IV and Rapid, also making a contribution towards marketing.

AFT sees potential for the new agreement to deliver greater commercial benefits than envisaged by the original agreements with Hikma, one of the largest suppliers of injectable medications by volume in the US.

US healthcare costs associated with opioid abuse are estimated at US\$11 billion a year<sup>7</sup>. With 6% of patients administered an opioid postoperatively observed to

---

<sup>2</sup> <https://ourworldindata.org/data-insights/the-united-states-has-by-far-the-highest-death-rate-from-opioids>

<sup>3</sup> Non-steroidal anti-inflammatory drugs

<sup>4</sup> Busse, J. (2017). The 2017 Canadian guideline for opioids for chronic non-cancer pain. Hamilton, Ont.: McMaster University.

<sup>5</sup> <https://www.grandviewresearch.com/horizon/outlook/analgesics-market/canada>

<sup>6</sup> <https://www.mordorintelligence.com/industry-reports/pain-management-market>

<sup>7</sup> <https://premierinc.com/newsroom/press-releases/opioid-overdoses-costing-u-s-hospitals-an-estimated-11-billion-annually>

consume the medicine chronically<sup>8</sup>, the two forms of Combogesic offer clinicians an opportunity to reduce these risks in post operative pain setting.

### **EXTENDING MAXIGESIC IV TO PAEDIATRIC POPULATION**

We are meanwhile preparing to commence a Maxigesic IV study for the paediatric population. The paediatric population typically has fewer safe and effective options for managing pain, particularly in hospital settings.

A significant number of physicians have already shown keen interest in data for this population. We expect the study to generate the clinical data required to support regulatory approvals and ensure appropriate dosing for children which will further extend the patient population and sales.

### **PRE-IND ANTIBIOTIC RESISTANT EYEDROP APPLICATION LODGED WITH FDA**

Our antibiotic eyedrop R&D is advancing with the pre-IND (Pre-Investigational New Drug) already filed with the US Food and Drug Administration (FDA) and we are targeting an IND application well before year-end.

A pre-IND request is an essential early step, allowing AFT to discuss preclinical data and study design with FDA guidance. The subsequent IND filing will pave the way for human clinical trials starting next year within the FDA's phased approval framework.

Licensed in 2023 from Latitude Pharmaceuticals, the antibiotic drop addresses resistant ocular infections such as the MRSA<sup>9</sup> superbug and is presently widely prescribed in the US as a compounded formulation but importantly no registered formulation is available.

Additionally, good progress has been made for the Topical Strawberry Birthmarks project with a pre-IND application in preparation for filing this year. Also following a successful pre-IND meeting, an IND application is in preparation for the novel injectable iron recently in-licensed with filing planned around the end of this year.

With a significant global market potential, these projects are expected to underpin the future growth of the company.

AFT's R&D pipeline now comprises 14 projects, featuring five candidates (multiple Maxigesic dose forms, Capsaicin creams, Crystaderm®, Kiwisoothe®, and Micolette®) nearing or in the commercialisation phase.

AFT has also added an improved formulation project targeted at a niche global market of around US\$180M which is planned to be ready for filing within next financial year.

Notably this last quarter has seen AFT complete five separate out-licensing agreements with a significant number of agreements and term sheets still under negotiation.

*For and on behalf of AFT Pharmaceuticals Limited by Malcolm Tubby, Chief Financial Officer.*

---

<sup>8</sup> <https://jamanetwork.com/journals/jamasurgery/fullarticle/2618383>

<sup>9</sup> Methicillin Resistant Staphylococcus Aureus

**For more information:****Investors**

Dr Hartley Atkinson  
Managing Director  
AFT Pharmaceuticals  
Tel: +64 9488 0232

**Media**

Richard Inder  
The Project  
Tel: +64 21 645 643

**About AFT Pharmaceuticals**

AFT is a growing New Zealand based multinational pharmaceutical company that develops, markets, and distributes a broad portfolio of pharmaceutical products across a wide range of therapeutic categories which are distributed across all major pharmaceutical distribution channels: over the counter (OTC), prescription and hospital. Our product portfolio comprises both proprietary and in-licensed products, and includes patented, branded, and generic drugs<sup>10</sup>. Our business model is to develop and in-license products for in our markets of Australia, New Zealand, Singapore, Malaysia, Hong Kong, USA, Canada, EU ex Ireland and UK, and to out-license our products to local licensees and distributors to over 125 countries around the world. For more information about the company, visit our website [www.aftpharm.com](http://www.aftpharm.com).

---