



3 November 2022  
NZX/ASX Market Release

## **FDA approval to supply infant milk formula to the United States**

The a2 Milk Company (a2MC, the Company) advises that the United States (US) Food and Drug Administration (FDA) has notified the Company that it has exercised its discretion to allow a2MC to import infant milk formula (IMF) products into the US.

Following the onset of IMF supply disruption in the US, FDA Guidance was released on 16 May 2022 in relation to case-by-case consideration of enforcement discretion to be applied to companies with the goal of increasing IMF supplies. a2MC applied to the FDA on 26 May 2022 under its enforcement discretion to supply IMF to the US. As announced by the Company on 10 August 2022, the FDA had deferred further consideration of a2MC's application for enforcement discretion. However, the Company has continued to engage with the FDA to meet its requirements and to reconsider a2MC's application.

Pleasingly the Company has today received confirmation from the FDA that its application for enforcement discretion to import, sell and distribute a2 Platinum<sup>®</sup> IMF product (Stages 1 and 2) from New Zealand into the US has been approved through to 6 January 2023. The Company is also able to supply Stage 3 toddler product in addition to this which does not require enforcement discretion.

The FDA published its Infant Formula Transition Guidance on 30 September 2022 applicable to companies with enforcement discretion that are seeking to obtain permanent approval to supply IMF into the US. Under certain conditions, the transition guidance allows enforcement discretion to be extended through to 18 October 2025 to enable such companies to comply with statutory and regulatory requirements. Any extension is subject to compliance with the FDA's infant formula transition guidance and ultimately FDA approval.

Product to be supplied to the US has the same formulation as a2 Platinum<sup>®</sup> but has different scoops, mixing instructions and labelling requirements to meet the FDA requirements. This product is not currently available in inventory and needs to be manufactured as soon as possible. a2MC previously indicated to the FDA that if approval was obtained by 30 September 2022, it had the capacity through Synlait Milk Limited (Synlait) to manufacture 9 million cans of a2 Platinum<sup>®</sup> (equivalent to 211 million 8oz bottles) by 30 June 2023 if required during the supply shortage period subject to customer demand. Whilst supply plans will need to be updated, it is expected that Synlait will have substantially the same capacity to supply such volumes over a nine-month period which is well within the limits of a2MC and Synlait's past production volumes.

a2MC believes the US represents a significant opportunity to develop its brand in the IMF category over the long term. However, at this early stage, it is difficult to predict the IMF sales potential in the US which is a highly competitive market to enter. Accordingly, the Company believes sales will be significantly below indicated manufacturing capacity unless the situation changes. In the near-term, and prior to confirming distribution plans,

sales during FY23 are expected to be up to 1 million cans all within 2H23, assuming enforcement discretion remains in place throughout the period. Actual sales will ultimately depend on customer demand, consumer offtake, supply shortages and market conditions at the time.

In terms of FY23 earnings impact, whilst incrementally beneficial, the Company expects gross margins to be lower than average, distribution costs to be higher due to potential air freight and rework costs in the near term, and incremental marketing and trade investment to enter the category. The Company will provide an update on US IMF distribution gains and sales outlook in connection with its 1H23 interim results release or earlier as appropriate.

The a2 Milk Company's Managing Director and CEO, David Bortolussi, said: "We are pleased to be able to assist parents and caregivers in the US by providing access to significant volumes of high quality, a2 Platinum® infant and toddler milk formula manufactured in New Zealand during this challenging period. Our a2 Platinum® product meets the FDA's food safety and nutritional requirements and is made with a2 Milk™, which has digestive and other potential health benefits that have underpinned the success of our brand in other markets.

"a2MC is well positioned to support this initiative being one of the leading premium international infant milk formula brands with annual sales exceeding 30 million cans. We have scalable production capacity in New Zealand with Synlait plus existing a2MC US sales, marketing and supply chain capability that can be leveraged.

"We are increasing our supply to respond to this situation, while importantly ensuring that we continue to meet the needs of our other IMF consumers and trade partners in China and other markets. If the US requires further support over an extended period, we have the proven ability to scale up significantly."

a2MC's Chief Executive in the US, Blake Waltrip said, "Over the past seven years, we have invested in developing our liquid a2 Milk® business in the US based in Boulder, Colorado. We currently supply a2 Milk® Whole, 2% Reduced Fat, Fat Free, Half and Half and HERSHEY's a2 Milk® with nationwide distribution to approximately 27,000 stores in the grocery, mass, natural and club channels. We have established customer relationships with all major retailers, many of which have expressed strong interest in ranging our a2 Platinum® product."

## **Authorised for release by**

**David Bortolussi**

**Managing Director and Chief Executive Officer**

**The a2 Milk Company Limited**

## **For further information, please contact:**

### **Investors / Analysts**

David Akers

Group Head of Investor Relations and Sustainability

M +61 412 944 577

[david.akers@a2milk.com](mailto:david.akers@a2milk.com)

Rebecca Culbertson

Investor Relations Manager

M +61 400 955 295

[rebecca.culbertson@a2milk.com](mailto:rebecca.culbertson@a2milk.com)

### **Media**

Rick Willis

M +61 411 839 344

[rick@networkfour.com.au](mailto:rick@networkfour.com.au)

### **Media – New Zealand**

Barry Akers

M +64 21 571 234

[akers@senescallakers.co.nz](mailto:akers@senescallakers.co.nz)