



Bubs Australia Limited
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Clinical Trial Update: Significant milestone achieved with 400th infant patient enrolment

Bubs Australia Limited (ASX:BUB) (“**Bubs**” or “**the Company**”) is pleased to announce that the 400th infant has now been enrolled in the Growth Monitoring Study (**GMS**). The GMS and clinical trial are being conducted as part of the regulatory requirement and guidelines set by the U.S Food and Drug Administration (**FDA**), for permanent access to the United States infant formula market. Bubs will transition from ‘temporary enforcement discretion’ to permanent market access, upon FDA approval, expected in October 2025.

This represents an incredibly significant milestone in what is a particularly robust clinical trial. Bubs’ first infant was enrolled in the GMS in late August 2023 and, to complete the enrolment within 13 months in a very competitive market, is testament to Bubs, focus, agility and the clinical trial experience and expertise of Bubs’ advisers and contract research organisation.

Bubs’ clinical trial involves a nationwide Growth, Tolerance, and Safety study of healthy term infants consuming Bubs’ infant formulas, monitored by healthcare professionals. The study evaluates all three stage 1 formulas in the market including Goat Milk, two Cow Milk products as well as a commercially available formula as the control. Additionally, the study contains a breast-feeding cohort for reference. Infant growth during the study is measured by healthcare professionals at designated clinical sites, with additional input from parents and caregivers.

Bubs’ clinical trial is overseen by principal investigator Dr. Keith Aqua, who is the co-founder of the HCA Florida Institute for Women’s Health and Body and the co-founder of Visions Clinical Research. Dr. Aqua is Board-certified in obstetrics and gynecology. As a Certified Physician Investigator, Dr. Aqua has been a Principal Investigator on over 350 clinical trials.

Importantly, Bubs’ 400th infant enrolment is a demonstration of Bubs’ meaningful progress throughout all aspects for the regulatory process in line with the FDA transition guidelines, following Bubs’ earlier completion of the ‘protein efficiency ratio study’, and Bubs’ submission of the ‘generally accepted as safe’ application. Bubs intends to formally submit the completed GMS and clinical trial documentation to the FDA early in 2025 with the FDA’s regulatory approval expected in October 2025.

Bubs first began importing its infant formulas into the United States in May 2022 as a response to the infant formula shortage that year. Bubs was the first company to offer assistance from abroad, participating in the US government’s ‘Operation Fly Formula’ program, and Bubs was the 2nd company in the world to be granted ‘temporary enforcement discretion’. Since then, Bubs has been steadily building its premium branded infant formula portfolio of evidence based clean label nutrition for American families, caregivers and pediatricians and has now cemented its position as the leading goat milk formula brand in the United States.

“Bubs continues to enjoy a relationship with US parents, caregivers and healthcare professionals based upon trust. Since first entering the US market in 2022 at a time of critical consumer need, Bubs has continued to make meaningful progress throughout the clinical trial. With our 400th infant now enrolled in the study, Bubs can finalise and submit the necessary data to the FDA in what is a critical step towards achieving permanent market access. We are pleased to have finalised patient enrolment in a significant study involving three distinct Bubs Infant Formulas,” said Richard Paine, Chief Operating Officer.

This release is approved by the Board of Directors

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ABOUT BUBS AUSTRALIA LIMITED (ASX: BUB)

Founded in 2006 in Australia, Bubs' purpose is to grow happy, healthy families through clean nutrition. Bubs® A2 Beta-Casein Protein, Bubs Organic® Grass-fed, and Easy-Digest Goat Milk Infant Formula, along with Bubs Organic® baby food range, cater for all feeding occasions and stages of a child's development during their first 1,000 days of life.

Bubs® products are widely sold in major supermarkets and pharmacies throughout Australia, as well as exported to nine markets across China, Southeast Asia, the Middle East, and USA.

Consumer Website:

bubsaustralia.com

Investor Centre:

investor.bubsaustralia.com