

ASX: ALA

Arovella Therapeutics Limited
ACN 090 987 250



February 5, 2026

BECOMING A CLINICAL-STAGE COMPANY

Dear Arovella Shareholders, Colleagues and Friends,

We are well into 2026 and believe it is an ideal time to pause, reflect, and explain the significance of the Investigational New Drug (IND) application acceptance for ALA-101 by the U.S. Food and Drug Administration (FDA). The acceptance of the IND marks a pivotal milestone for the Company and validates Arovella's preclinical data and clinical development plan. Most importantly, it also confirms the extensive work in developing our manufacturing process for CAR-iNKT cells, which we expect to be applicable not just for a single therapeutic, but for each product that we look to develop moving forward. The manufacturing capability, developed over the last four years, now forms the core of Arovella's intellectual property and will over time potentially become the leading value driver within our Company.

Taking ALA-101 into clinic for patients with CD19-positive lymphoma and leukaemia

Arovella finished 2025 strongly, and the team did an excellent job submitting the IND for ALA-101 on 30 December 2025, allowing us to receive positive feedback from the U.S. FDA early in 2026. Securing the IND means we now have a proprietary CAR-iNKT cell therapy manufacturing process for ALA-101 that is IND approved, and the accepted IND enables us to initiate our phase 1 clinical trial this year as planned for patients with CD19-positive blood cancers. With the IND clearance in place, the pathway is clear, engage and contract clinical sites, secure Human Research Ethics Committee (HREC) approval, finalise manufacturing of the clinical material, and screen, enrol and dose the first patient. We are working with our contract research organisation (CRO) partner, SAPRO, to accelerate these activities and look forward to providing updates to Shareholders as we progress. We are very excited to dose the first patient with ALA-101, as it represents a unique opportunity for patients as one of very few commercial CAR-iNKT cell products being developed.

Expanding the pipeline

The IND signifies more than just an approval to start clinical trials for ALA-101. Arovella's proprietary CAR-iNKT cell manufacturing process has been developed to enable the development of new therapeutics targeting diverse cancers without substantially modifying the manufacturing process. To advance future products, we expect only one major raw material to change, the lentiviral vector, which carries the DNA sequence to incorporate the CAR into the iNKT cells and defines which cancer(s) can be targeted. As such, we expect development of future programs to occur more swiftly and cost-effectively. Given the platforms modular nature, we expect the long-term value of the Company to be significant because of this carefully designed strategy.

Since licensing the CAR-iNKT cell platform, we have continued to search for additional CARs that enable us to target different cancer types. To that effect, we continued to broaden our pipeline by strengthening our strategy in solid tumours, including programs directed at gastric and pancreatic cancers. We demonstrated that our CAR targeting CLDN18.2 can robustly eliminate pancreatic cancer cells that have CLDN18.2 on their surface. It is important to reiterate, CLDN18.2 is an exciting target and clinically validated through the approval of Zolbetuximab in Japan and the U.S. to treat HER2-negative and CLDN18.2-positive gastric cancer.

We look forward to generating and sharing further data for this program once we integrate the Arovella CLDN18.2-targeting CAR into our iNKT cell platform. We are also excited to test this alongside our armouring strategy, IL-12-TM, which has been shown to enhance the function and cancer cell killing ability of CAR-iNKT cells. We anticipate being able to present additional data in the near-term.

We were also pleased to exercise the Option from Baylor College of Medicine (Baylor) towards the end of 2025. The two CARs under the Exclusive Option target GD2 and GPC3, which are clinically validated targets for solid tumours, with early-stage results from FDA IND-enabled clinical trials. Significant capital and resources have been invested developing these CARs, which provides an excellent foundation for Arovella to build on. We are excited to continue the discussion as we move forward with the definitive license agreement.

Expanding the team

Throughout 2025, we made several high-quality additions to the team. In preparation for the phase 1 clinical trial, we appointed Jacqueline Cumming as our Senior Director of Clinical Development. She has an exemplary background leading clinical trials, initially at CSL and more recently within the Peter MacCallum Cancer Centre. Two talented scientists, Dr Alfie Baker and Dr Sarah Sandford, were recruited to lead activities in our newly established laboratory within the Jumar Bioincubator. This is an important extension of our R&D efforts. Additionally, we entered into a Sponsored Research Agreement (SRA) with the University of North Carolina and in the process recruited a skilled scientist, Dr Clinton Heinze, to lead R&D activities related to the CLDN18.2 CAR program and the IL-12-TM armouring strategy.

We were also pleased to appoint Dr Andrew Nash to our Board of Directors. Dr Nash brings over 35 years of practical drug development experience and executive leadership in the biotech and pharmaceutical sectors, most recently with Australia's largest and most successful pharmaceutical company, CSL. Dr Nash initially trained as an academic scientist after completing his PhD in Immunology. He then joined Zenyth (formerly Amrad Corp), where he advanced to become CSO, and ultimately CEO before it was sold to CSL in 2006. Dr Nash was appointed CSO of CSL in 2020 and remained in that position until his retirement in March 2025. We are delighted to have him on the board, and the intention is for Andrew to transition to Chairman of the Board at the appropriate time. We look forward to providing updates in due course.

Strong Financial Position

The Company has a very strong balance sheet, finishing 2025 with \$19.4 million cash in the bank. This positions the Company well as we begin phase 1 clinical trials with ALA-101 and provides funding to reach early clinical safety and efficacy readouts. In addition, it provides support for our additional products, including ALA-105, which is targeting target gastric cancer and pancreatic cancer. We look forward to being careful stewards of the capital as we work to tick off critical milestones for each of our programs.

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Summary and outlook for 2026

Overall, Arovella is in an excellent financial position and is on the verge of advancing ALA-101 into clinical trials. We are preparing for what promises to be a defining year for the Company. We expect to start clinical dosing for ALA-101, marking the first time our CAR-iNKT technology will be used in patients. Delivering initial safety and early efficacy data will be an important step in confirming the promise of our platform. Alongside this, we plan to advance our solid tumour candidates and continue integrating enhanced armouring technologies to strengthen their potential impact. As the Company enters a more data-driven stage of development, we also anticipate expanding our network of clinical, scientific and commercial partnerships to support both execution and scale.

The collective effort from our team, collaborators and Board members — along with the ongoing support of our shareholders — has brought us to an exciting new phase. I am tremendously proud of what we have achieved together and equally enthusiastic about what lies ahead. This is a transformational time for the Company, and we would like to extend a sincere thank you to shareholders that have supported us over the past 4 years, as we took a technology from the research stage and into clinical trials. Thank you for your continued confidence and commitment to Arovella.

We look forward to sharing an exciting 2026 with you.

Warm regards,

A handwritten signature in blue ink, appearing to read "Michael Baker".

Dr Michael Baker

Chief Executive Officer & Managing Director
Arovella Therapeutics Limited