ASX Announcement | 18 September 2026

AdAlta Limited (ASX:1AD)

Landmark US$120 million agreement for Oribiotech validates AdAlta's chosen CAR-T manufacturing automation platform

Oribiotech has signed a 10-year partnership, worth up to US$120 million, to bring an existing commercial cell therapy onto the same IRO® manufacturing platform AdAlta aims to deploy for its own cellular immunotherapies

Investment highlights

- Oribiotech ("Ori"), AdAlta's cell therapy manufacturing automation partner, has signed a **10-year agreement worth up to US$120 million** with an undisclosed commercial stage partner to integrate its IRO® platform into the manufacture of an already approved and commercialised cell therapy.
- A commercial stage biopharmaceutical partner is **exactly the profile of the intended buyer or commercialisation partner** of AdAlta's cellular immunotherapies – and **their manufacturing platform choices are an important indicator of what they will expect of AdAlta**.
- AdAlta, Ori and Cell Therapies Pty Ltd ("CTPL") **signed a Memorandum of Understanding in April 2026** to deploy IRO® for AdAlta's cellular immunotherapy pipeline.
- **Ori's new commercial partnership validates this choice**: future AdAlta products developed on IRO® will be made on a platform industry has **already validated and put into commercial use**.
- IRO® is designed to deliver **10 to 50 times more output from the same footprint and 30-50% lower manufacturing costs**, with more consistent product quality.
- EW-001, licensed prior to the Ori collaboration, already has its own low cost, rapid and scalable manufacturing solution and so will not be made on IRO®.
- IRO® compatibility is now a design priority for AdAlta's future products.

Melbourne, Australia: AdAlta Limited (ASX:1AD) ("AdAlta" or "the Company"), developer of next generation cellular immunotherapies for solid cancers, welcomes the announcement by its cell therapy manufacturing automation partner, Oribiotech Ltd ("Ori"), of a 10-year partnership worth up to US$120 million under which Ori's IRO® platform will be integrated into a biopharmaceutical company's existing commercial cell therapy manufacturing process.

Reliable, scalable and portable (across sites) manufacturing processes assume outsized importance for cellular therapies, ranked equally with clinical outcomes by investors and large biopharma companies alike. AdAlta, Ori and Australian contract manufacturer Cell Therapies Pty Ltd ("CTPL") signed a Memorandum of Understanding in April 2026 to deploy IRO® in Australia and the Asia Pacific for AdAlta's own cellular immunotherapy pipeline. Ori's announcement means the platform AdAlta is adopting has now been chosen by a company that already manufactures and sells an approved cell therapy – and chosen not for an early-stage product, but to take over a process that is already running commercially in order "to modernize the partner's autologous cell therapy manufacturing infrastructure with the aim of expanding patient access to current and future potentially transformative cell therapies".[1]

AdAlta CEO and Managing Director, Dr Tim Oldham said:

"Congratulations to Jason Foster and the whole Oribiotech team. Winning a ten-year commitment of this size for an approved, marketed cell therapy is a remarkable achievement, and it says something important for AdAlta shareholders. When we chose to deploy IRO® we were backing a view that automation is what separates a cell therapy that merely works from a cell therapy that can be sold. A commercial manufacturer

[1] https://oribiotech.com/press-releases/ori-biotech-announces-10-year-120m-partnership-to-advance-automated-manufacturing-for-commercial-cell-therapies

has now looked at the same platform and decided to move an already-approved product onto it. Nobody takes that decision lightly – it is the highest bar in our industry.

It means the cellular immunotherapies we develop on IRO® will be made on a platform that our eventual partners have already validated, endorsed and put into commercial use. That takes a significant question off the table in any future partnering conversation."

Why moving a commercial process is such a strong endorsement
Cell therapy manufacturing is critical to the commercial success or failure of these products. Each product is manufactured individually for each patient, an expensive and complex process. Each patient's cells behave slightly differently, and small changes in the equipment and conditions used in manufacturing can impact product efficacy and safety.

Cell therapy companies change their manufacturing processes reluctantly, and almost never once a product has been approved. Each patient's dose is made individually from living cells, so the process is effectively part of the product. A company that changes it must demonstrate **comparability** to regulators – evidence that therapy made the new way performs the same way in patients as therapy made the old way. That work takes time and money and carries real risk.

A biopharmaceutical company with an approved, commercially marketed cell therapy has now decided that the advantages of automating on IRO® outweigh that cost and risk, and has committed to a decade-long relationship and up to US$120 million to pursue it. For AdAlta, that is a far more powerful signal than any pilot study. The companies that ultimately buy products like AdAlta's are not merely trialling automated manufacturing – they are prepared to move commercial production onto it.

What IRO® brings to AdAlta's products
IRO® is a fully closed, automated system that carries a cell therapy process from research through to commercial manufacture on a single platform. The benefits, described when the AdAlta, Ori and CTPL Memorandum of Understanding was announced in April 2026, are:

- **Cost.** Potential manufacturing cost reductions of 30-50%. The cost of making these therapies is a central reason they remain out of reach for most patients.
- **Capacity.** Ten to fifty times more patient doses from the same physical footprint, without building additional clean rooms.
- **Consistency.** Automating and digitising labour-intensive manual steps reduces variation between batches and the risk of a failed dose.
- **One platform, start to finish.** A process developed on IRO® scales to commercial manufacture without being rebuilt, and transfers between sites more readily.

Cost, capacity, consistency and transferability are what decide whether a cell therapy that works in a clinical trial can be supplied profitably to large numbers of patients. They are also the questions a pharmaceutical partner asks first.

Next steps and strategic significance
EW-001, AdAlta's lead CAR-T cell therapy, was selected in part because it already had a robust, low cost, scalable manufacturing process implemented. That process is being transferred from Shanghai Cell Therapy Group Co Ltd ("SHcell") to CTPL and does not benefit from being run on IRO® in its present form.

For the products that follow, IRO® compatibility is now a design priority: AdAlta is prioritising East to West candidates whose manufacturing can be built on IRO® from the outset. This ensures that AdAlta has a large biopharma preferred manufacturing solution available for its pipeline, increasing the pool of innovative products from which it can source its pipeline.

For shareholders, the significance is straightforward. AdAlta's value is realised through partnerships with, or sales to, larger pharmaceutical companies, and manufacturing is one of the areas those companies scrutinise most closely. A product developed on IRO® arrives at that conversation on a platform the industry has already validated, endorsed and deployed and avoids the comparability work that Ori's new customer has taken on. IRO® deployment at CTPL under the April 2026 Memorandum of Understanding will commence once active discussions to license a suitable next product are concluded.

To view a summary, and engage in discussion about this announcement visit AdAlta's InvestorHub here: https://investorhub.adalta.com.au/link/eYOnWP

This ASX announcement has been authorised for release by the Board of AdAlta Limited (ASX:1AD).

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About EW-001 (formerly BZDS1901)

EW-001 is a novel, first in class, CAR-T cell therapy designed to treat mesothelioma (a rare but rapidly fatal cancer usually linked to asbestos exposure) and with possible application in more than ten other cancers. CAR-T cell therapies are living drugs manufactured from a patient's own immune cells that are engineered to be able to find and kill cancer. They offer the potential to provide durable cancer control or cure from a single treatment. EW-001 targets a protein called mesothelin that is highly expressed in many cancers. EW-001 is also engineered to product a protein called a checkpoint inhibitor that is designed to protect the CAR-T cell from a key defensive mechanism used by cancers.

Patients diagnosed with mesothelioma today are typically treated with surgery if possible and then initial or first line drug treatments are chemotherapy or immunotherapy. Once a patient has relapsed after initial therapy, second line treatment options are even more limited and outcomes are much poorer. Current treatments typically deliver: [2,3]

- Tumour shrinkage (Overall Response) in only 40-44% of first line patients and 11-29% of second and subsequent line patients
- Complete tumour clearance (Complete Response) is rare and seen in less than 3% of first line patients and almost never in second line patients
- Median survival (at which point 50% of patients will have died) is often only 14-18 months for first line and 8-10 months for second line treatment, with tumours beginning to grow again typically after only half that time.

By contrast, EW-001 clinical studies in relapsed or advanced mesothelioma patients (second line and later) in China have reported:

- Up to 50% Overall Response rate (tumour shrinkage)
- Up to 20% Complete Response rate (complete tumour clearance)
- Two patients achieving Complete Responses have now reached two and one year survival milestones respectively with no evidence of cancer returning providing evidence of durability of response
- Median overall survival has not yet been reached in the current generation manufacturing process, however an earlier generation of EW-001 achieved more than 25 months median survival

These early results suggest EW-001 may offer an exciting potential new treatment option for patients with few alternatives. EW-001 has not yet received regulatory approval for general commercial launch anywhere in the world.

About AdAlta

AdAlta (ASX: 1AD) is a clinical stage biotechnology business addressing the need for effective cellular immunotherapies for the treatment of solid cancers.

[2] CHECKMATE-743 study (nivolumab + ipilimumab against chemotherapy): S Peters et al, Annals of Oncology, 2022 (33) 488; https://doi.org/10.1016/j.annonc.2022.01.074
[3] See for example CONFIRM study (nivolumab against placebo): DA Fennell et al, Lancet Oncol 2021 (22) 1530

Through its ‘East to West’ strategy, the Company is integrating Asia's prowess in T cell therapy development with the efficiency and quality of Australia's clinical and manufacturing ecosystem to create a pathway connecting ‘Eastern’ innovation in cellular immunotherapies with ‘Western’ regulated markets and patients.

AdAlta in-licenses products from Asian originators and invests to establish US FDA regulated manufacturing and conduct Phase I clinical studies with potential to position each product for on-licensing to larger biopharmaceutical companies for potential registrational studies and commercialization.

AdAlta implements a disciplined approach to asset selection focused on highly differentiated T cell therapy products supported by clinical data in solid cancers. The company adopts a capital efficient business model delivering a rapid return on investment in each project that is replicable and provides opportunities to scale across multiple products.

Solid tumours account for 90% of cancers yet remain underserved by current cellular immunotherapies. AdAlta aims to dominate this high-growth segment. The cellular immunotherapy market is projected to grow at a compound annual growth rate of 34% to reach US$20.3 billion by 2028.

AdAlta’s other assets include first in class fusion protein, AD-214, that takes a whole new approach to fibrotic diseases of the lung and kidney, such as the degenerative and fatal Idiopathic Pulmonary Fibrosis and WD-34, a novel pan-strain inhibitor of malaria, babesisos and toxoplasma parasites. Following demonstration of efficacy in multiple animal models of disease and two successful Phase I clinical studies, AD-214 is available for partnering. WD-34 is seeking grant funding to optimize the molecule format to enable single dose seasonal prophylaxis.

To learn more, please visit: www.adalta.com.au

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