ASX Announcement | 4 February 2025
AdAlta Limited (ASX:1AD)

AdAlta to present at 3rd ANZ Biologics Festival

AdAlta Limited (ASX:1AD) ("AdAlta" or **"the Company")**, developer of next generation cell and protein therapeutic products is presenting at the 3rd ANZ Biologics Festival being held in Melbourne, Australia from 4-5 February, 2025. The 3rd ANZ Biologics Festival 2025 is the region's premier conference that aims to gather the innovators, pioneers, and leaders in the biologics fraternity, including Biologics, Biosimilars, Vaccines, Cell and Gene Therapy (CGT), and RNA Therapeutics, to showcase the latest from ideation to commercialization phase and beyond.

CEO and Managing Director, Dr Tim Oldham is presenting a paper entitled "Market Trends & Investment Landscape for Cell and Gene Therapy in ANZ" that is focused on the strength of the local cell and gene therapy ecosystem and the role Australia and New Zealand can play in the growth of the sector in Asia. The paper will conclude using AdAlta's "East to West" cellular immunotherapy strategy as one example of how this might be done. Dr Oldham will also participate in a leadership panel titled: "Roadmap to Transforming Healthcare: Cell & Gene Therapies in the ANZ Region."

Details of Dr Oldham's presentations are:

- *Market Trends & Investment Landscape for Cell and Gene Therapy in ANZ*
- 4th February 2025 10:25 AM AEST, Crowne Promenade Conference Centre

- *Leadership Panel: Roadmap to Transforming Healthcare: Cell & Gene Therapies in the ANZ Region*
- 4th February 2025 09:00 AM AEST, Crowne Promenade Conference Centre

A copy of the presentation is attached.

More information about the 3rd ANZ Biologics Festival can be found here: https://www.imapac.com/events/3rd-anz-biologics-festival-2025#register

For an opportunity to engage in a virtual discussion on this release see:
https://investorhub.adalta.com.au/link/lPdlYP

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

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About AdAlta Limited

AdAlta Limited is a clinical stage drug development company headquartered in Melbourne, Australia. The Company is using its proprietary i-body® technology platform to solve challenging drug targeting problems and generate a promising new class of single domain antibody enabled protein and cell therapeutics with the potential to treat some of today's most challenging medical conditions.

The i-body® technology mimics the shape and stability of a unique and versatile antigen binding domain that was discovered initially in sharks and then developed as a human protein. The result is a range of unique proteins capable of interacting with high selectivity, specificity and affinity with previously difficult to access targets such as G-protein coupled receptors (GPCRs) that are implicated in many serious diseases. i-bodies are the first fully human single domain antibody scaffold and the first based on the shark motif to reach clinical trials.

AdAlta's lead i-body® enabled candidate is AD-214. At any time, 500,000 patients with lung fibrosis (IPF) face death from inability to breath, despite spending US$4.3 billion per year on pharmaceutical therapies. Fibrosis can affect all organ systems and around 45% of all western country deaths have a fibrotic disease component. AD-214 is taking a wholly new approach to treat IPF and other fibrotic diseases. AD-214 is a first in class (first to utilize this mode of action) molecule and has been shown to be safe in Phase I clinical studies and effective in multiple animal and laboratory models of fibrotic disease. In accord with its business model, AdAlta is creating a private, unlisted subsidiary called AdSolis to advance AD-214 into Phase II clinical trials through licensing and/or third party investment.

AdAlta believes that the i-body® technology is ideally suited for use in the creation of advanced cellular immunotherapies for cancer and that this field represents an opportunity to expand its clinical stage pipeline. It has entered a Memorandum of Understanding with SYNthesis BioVentures to investigate the formation of a jointly owned entity, to be called AdCella, that, once established, will provide innovative cellular immunotherapies originating in Asia with a pathway to western regulated markets via Australian clinical trials and further enhancement with AdAlta's i-body® technology. It has appointed Cell Therapies Pty Ltd, Australia's leading manufacturer of cell and gene therapies, as AdCella's preferred manufacturer.

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

For more information

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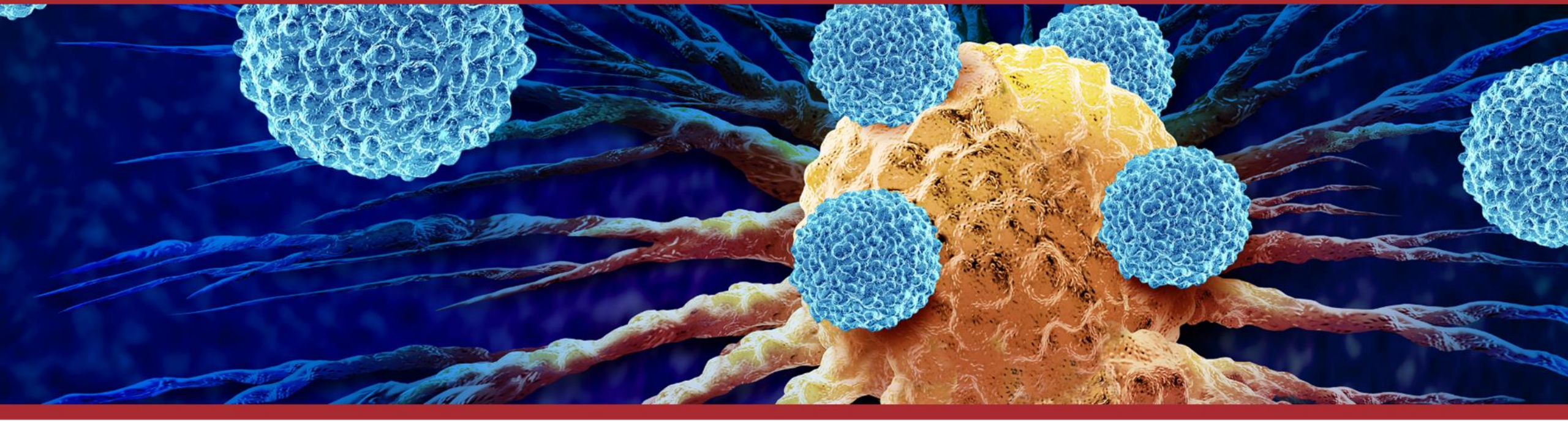
AdAlta



Market trends and investment landscape for cell and gene therapy in Australia

ANZ Biologics Festival 2025

4 February 2025

AdAlta overview: specialist in next generation cell and protein therapeutics

Specialist in next-generation cell and protein therapeutics for fatal diseases

"East to West" cell therapy strategy to position company for scalable growth in a high value rapidly growing market

- Leading in cellular immune therapies for solid cancer
- First assets under late-stage due diligence
- Team and network in place
- Distinctive positioning and risk profile

Attractive valuation

A$11.0m market capitalization (ASX:1AD)

A$8.5m EV + proforma A$2.5m cash

AD-214, a new approach for fibrotic diseases, available for partnering

- Phase I complete: Safety established
- Compelling pre-clinical data
- Competitively well positioned

Agenda today

- **C&GT industry by the numbers**
- C&GT industry by the science
- Opportunity Australia

The US Continues to Lead, but the Sector is Globalizing Fast

Interim 2024 Data

2024	Developers (Snapshot value)	Clinical Trials (Snapshot value)	Investment (2024 Total)
North America	1,230	981	$11.8B
Asia Pacific	1,029	879	$1.5B
Europe	581	384	$2.0B
Total (y/y growth)	2,936* ↑6%	1,975* ↑3%	$15.2B* ↑30%

Activity is high in Asia, financing lags

GlobalData.

*Totals refer to unique quantities and include data from other regions not shown

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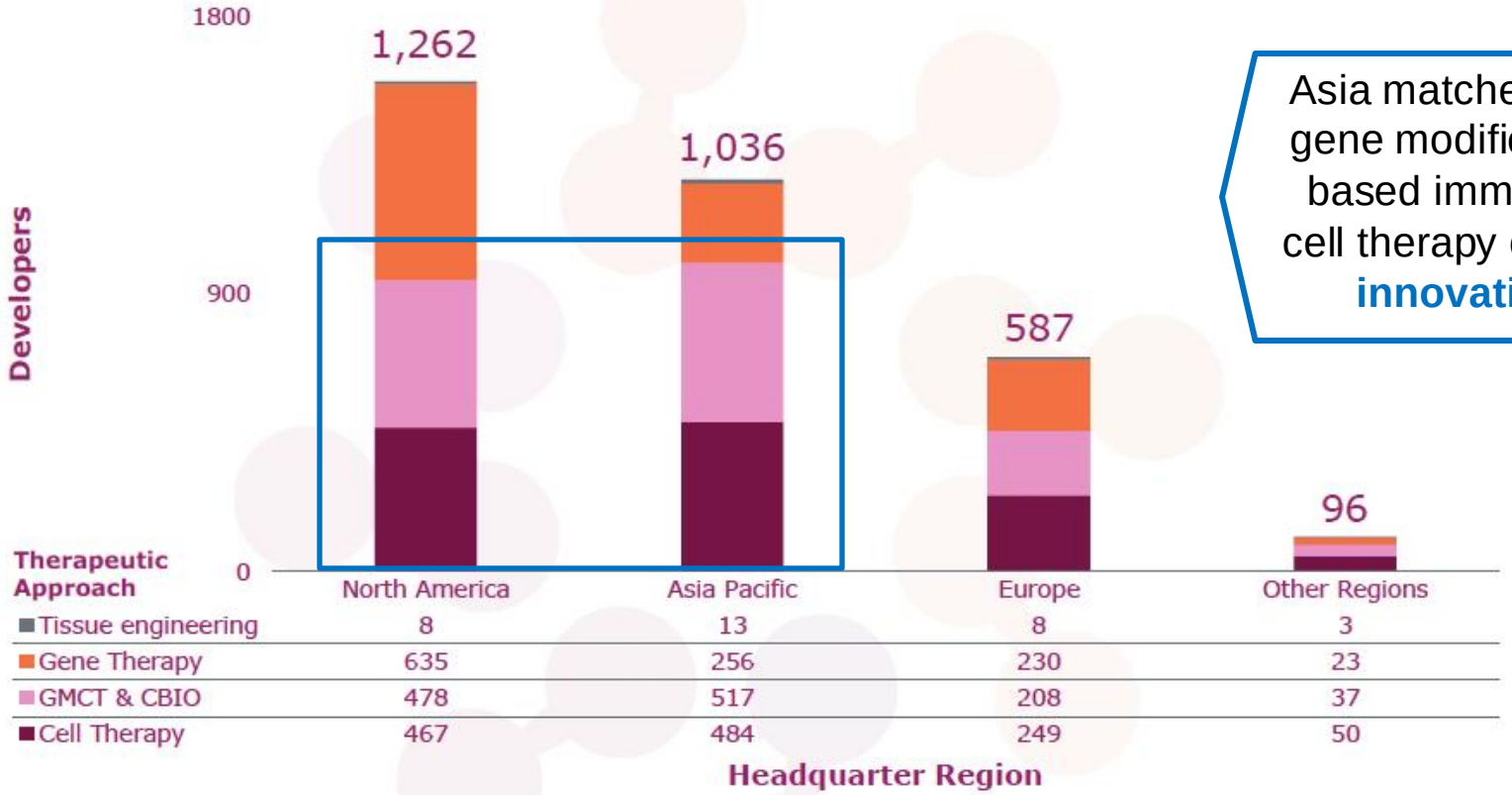
Source: Alliance for Regenerative Medicine, State of the Industry Address, JPMorgan Healthcare Week

Developers by Headquarter Region and Therapeutic Approach

Q3 2024



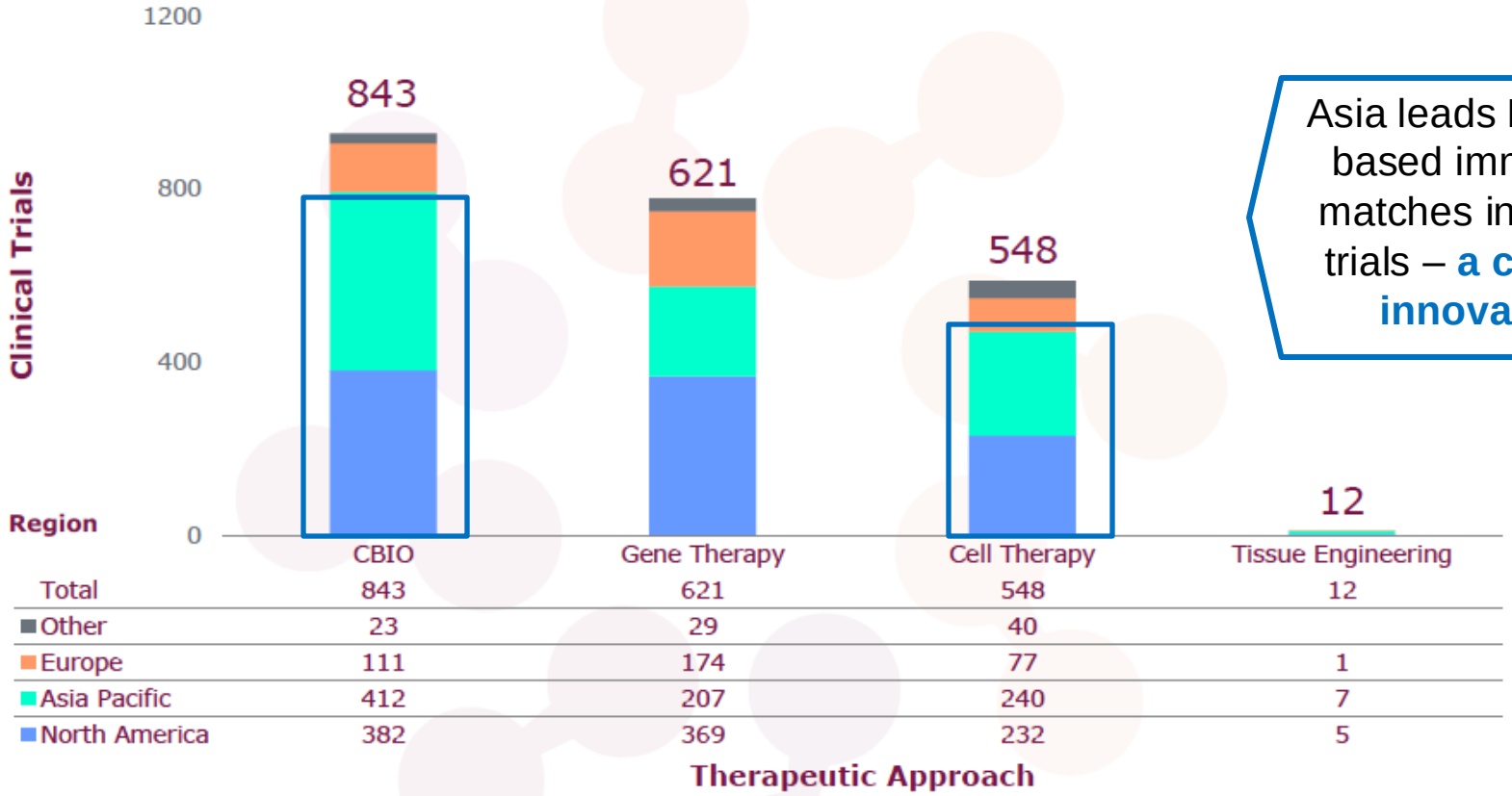
Asia matches North America in gene modified cell therapy, cell based immuno-oncology and cell therapy companies – **a rich innovation ecosystem**

1. Within-graph labels represent headquarter region totals
2. Developers may work across multiple therapeutic approaches; sum of therapeutic approach totals will not be equivalent to regional totals
3. Please see "Methodology Notes" for additional details

Source: Alliance for Regenerative Medicine, Q3 2024 Therapeutic Developers data pack

Ongoing Clinical Trials by Therapeutic Approach and Region

Q3 2024



	CBIO	Gene Therapy	Cell Therapy	Tissue Engineering
Total	843	621	548	12
Other	23	29	40	
Europe	111	174	77	1
Asia Pacific	412	207	240	7
North America	382	369	232	5

Therapeutic Approach

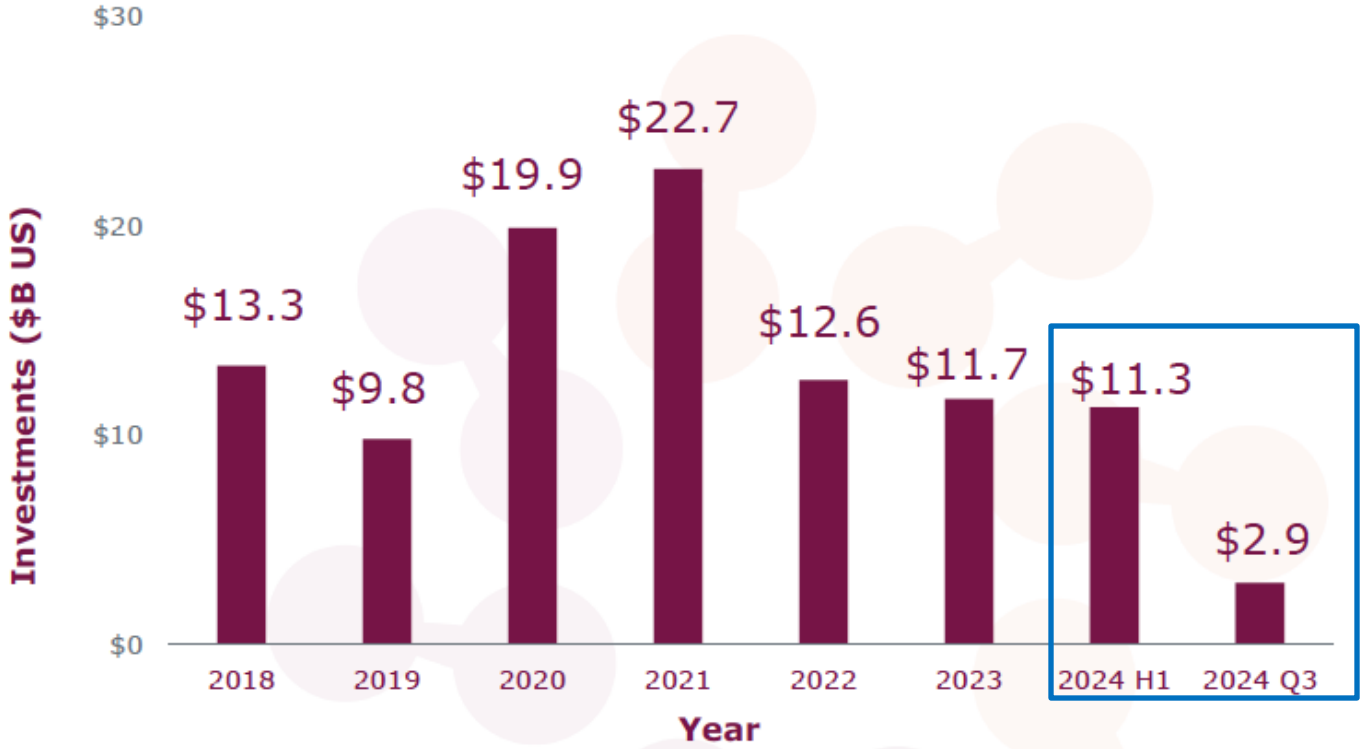
Asia leads North America in cell based immuno-oncology and matches in cell therapy clinical trials – **a clinically advanced innovation ecosystem**

1. Within-graph labels represent therapeutic approach totals
2. Clinical trials take place in multiple regions; sum of regional totals will not be equivalent to therapeutic approach totals

No major difference in mix of trials by Phase between regions

Source: Alliance for Regenerative Medicine, Q3 2024 Clinical Trials data pack

Investments by Year
Q3 2024

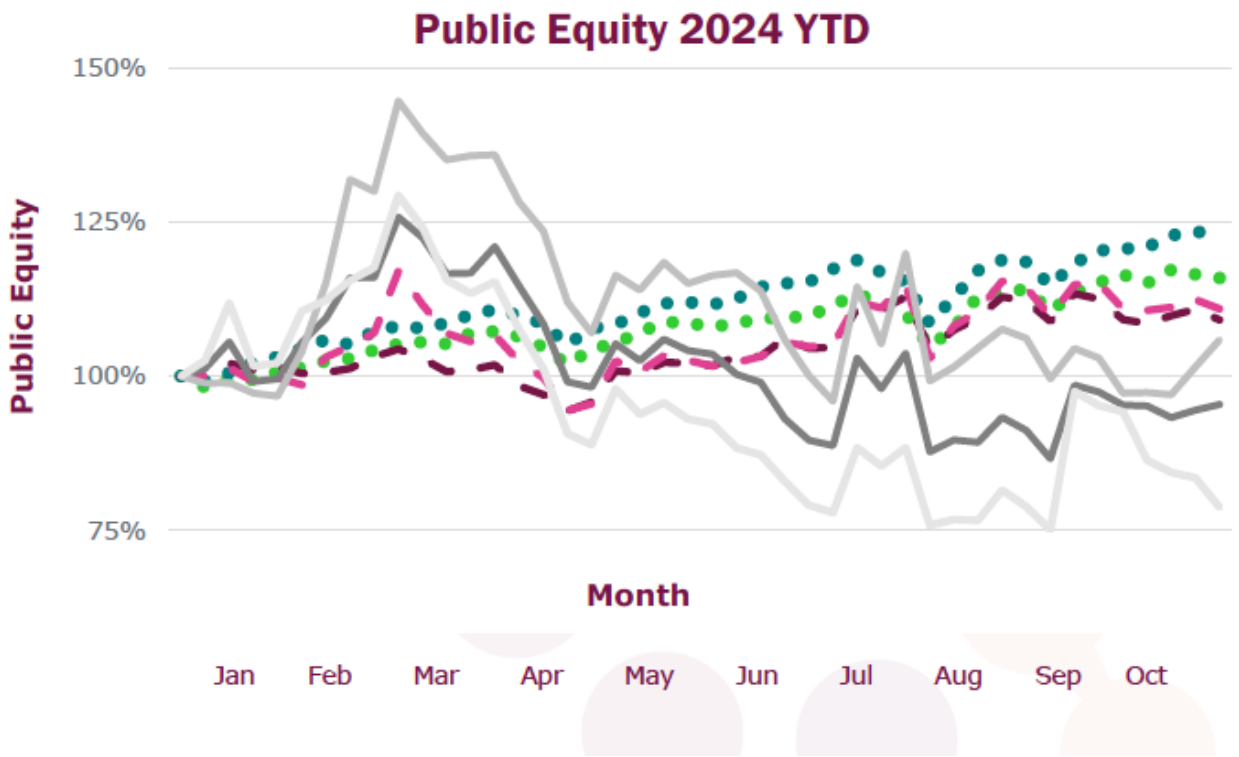


$14.2b Q3 YTD; $15.8b FY estimated new investment – **2024 global investment in cell and gene therapy is 3rd highest on record …**

Source: Alliance for Regenerative Medicine, Q3 2024 Deals data pack

Investments by Month

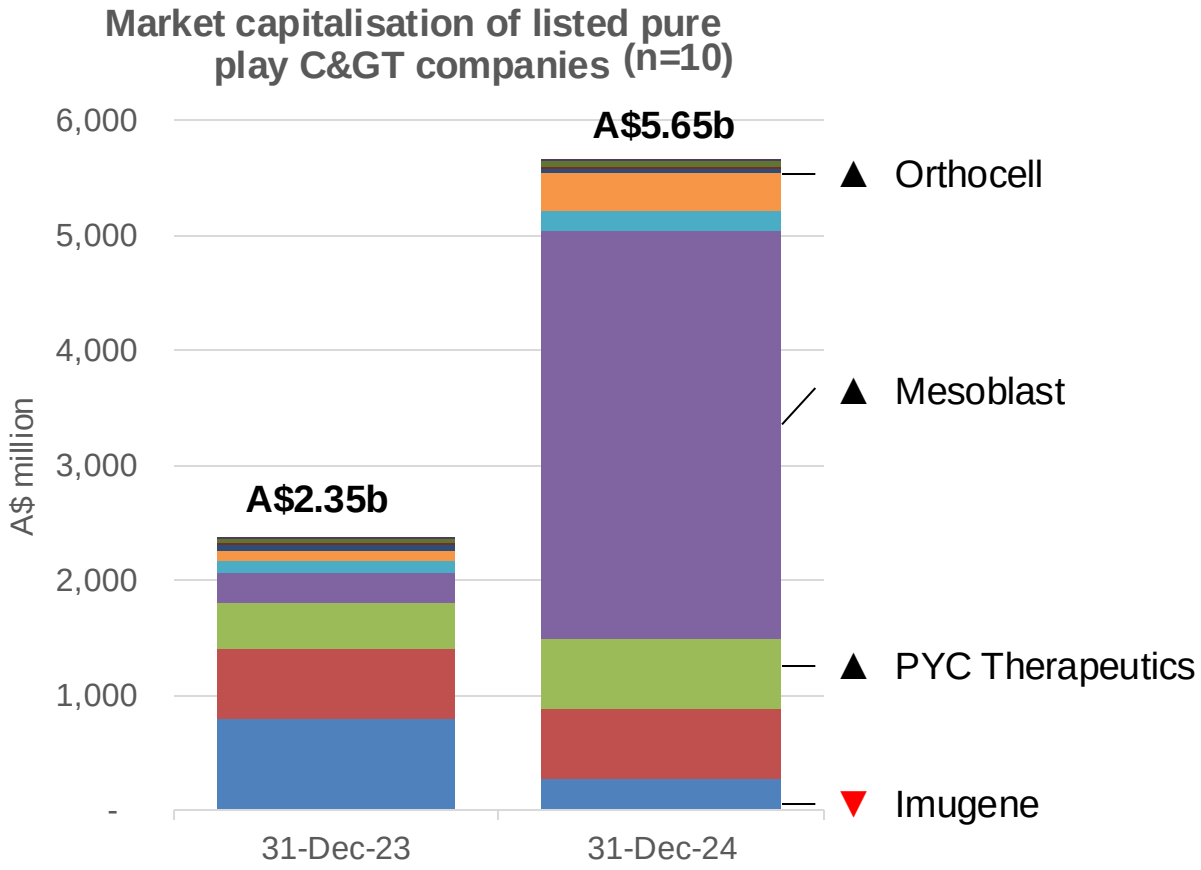
Q3 2024



… however valuations have not kept pace with broader biotech market

Source: Alliance for Regenerative Medicine, Q3 2024 Deals data pack

How Australia compares: strong year for cell therapies; clinical trials



Capital raising[1]

A$121 million capital raised by listed C&GT companies (n=10)

- **5%** of BioShares ASX biotech universe

>A$60 million raised by unlisted C&GT companies (n=11)

>A$181 million total

- **0.8%** of global total
- **8%** of APAC total

Clinical trials – cellular immunotherapies[2]

50 active cellular immunotherapy clinical trials

- **2.8%** of global total
- **4.5%** of APAC total

1. BioShares, company websites, AdAlta analysis; excludes $260m raised by Mesoblast in January 2025 and $135m invested by NSW government in Viral Vector Manufacturing Facility
2. GlobalData, AdAlta analysis

Agenda today

- C&GT industry by the numbers
- **C&GT industry by the science**
- Opportunity Australia

2024 sector highlights – selected and in no particular order

Global

1. FDA approves 9 new C&GT's (total now ~18)
2. 1st T cell therapies for solid cancers approved: TIL (Amtagvi for metastatic melanoma); TCR-T (Tecelera for synovial sarcoma)
3. 1st allogeneic MSC product approved by FDA: Mesoblast
4. Vertex, bluebird bio achieve outcomes based payment model with CMS for sickle cell gene therapies
5. CAR-T cell therapies move up lines of treatment
6. 1st *in vivo* CAR-T clinical trials (four)
7. CAR-T expansion into autoimmune disease (multiple in clinic)
8. Prime editing and epigenetic editing reach clinical trials
9. Roche gene therapy deals: ↑ Sarepta collaboration; adds Poseida Therapeutics ($1b), Dyno Therapeutics ($50m → $1b); ↓ Spark
10. Novartis expands gene therapy pipeline: $1.1b Kate Therapeutics acquisition; $1.3b deal with Voyager

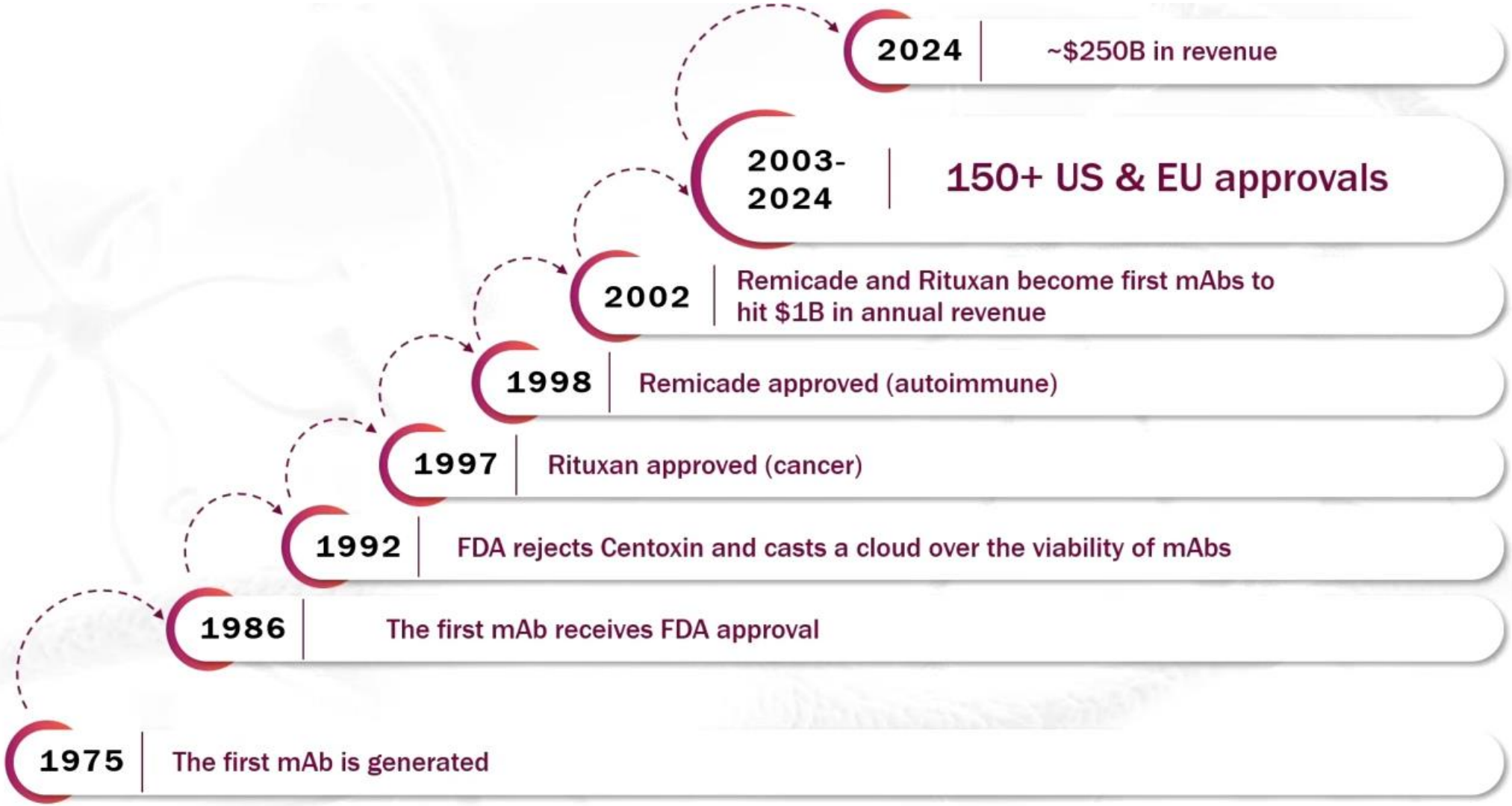
ANZ

1. Total of 11 gene and gene modified cell therapy product approvals (excludes unmodified cell and tissue therapy products)
2. TGA approval of CSL's Hemgenix gene therapy for haemophilia B
3. Mesoblast achieve FDA approval of 1st allogenic MSC product
4. Access to CAR-T for lymphoma expanded to 2L
5. Carina Biotech advance 1st "home grown", commercial solid cancer CAR-T into clinic
6. Three of four *in vivo* CAR-T cell therapy trials recruiting in Australia
7. BioOra raise funds to establish NZ's first manufacturing and clinical delivery capability for CAR-T; 1st CAR-T into Phase II
8. NSW Govt invests $134.5m in Viral Vector Manufacturing Facility

With apologies to any deserving companies, institutions or technologies missed

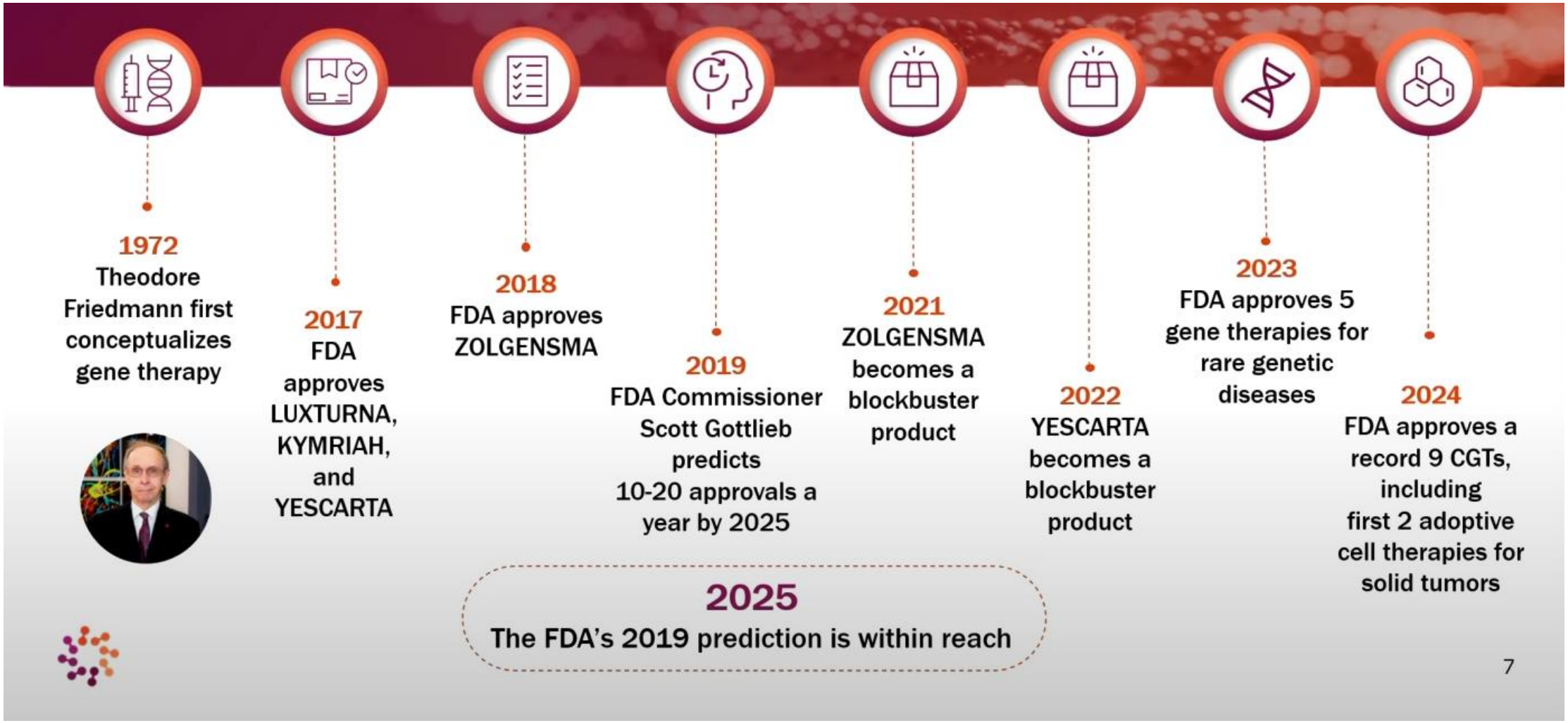
Source: Susan Nichols, Advanced Therapies Week 2025, Alliance for Regenerative Medicine December 2024 Sector Snapshot, press, company websites

The (long) journey of monoclonal antibodies to being a huge global market …



Source: Alliance for Regenerative Medicine, State of the Industry Address, JPMorgan Healthcare Week

… is now being mirrored by a similar, non-linear, journey of cell and gene therapies as US approvals ramp up …



Source: Alliance for Regenerative Medicine, State of the Industry Address, JPMorgan Healthcare Week

… blockbuster and large product numbers are forecast to grow …

Commercial Blockbusters
(with estimated >$1B worldwide sales)

- **2018** — *Global CGT revenue totals $450 million*
- **1** — **2021** — zolgensma
- **2** — **2022** — YESCARTA
- **4** — **2025** — CARVYKTI (ciltacabtagene autoleucel), Elevidys
- **10+** — **2030** — *Driven by currently launched and late-stage pipeline therapies (Analyst Consensus Data)*

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Success Beyond Blockbusters

From 5 CGTs today with $500M+ in annual worldwide revenue, to 30+ CGTs in 2030*

75% worldwide revenue — < 10 CGTs

75% worldwide revenue — ~50 CGTs

Source: EvaluatePharma (Analyst Consensus Data), Deloitte Analysis

**Includes currently launched and late-stage pipeline therapies*

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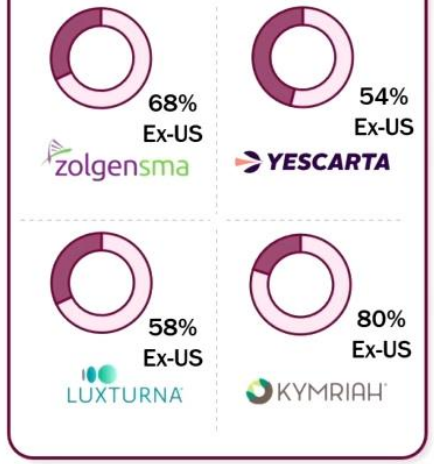
Source: Alliance for Regenerative Medicine, State of the Industry Address, JPMorgan Healthcare Week

… ex-US opportunities grow and big biopharma commits

Significant Commercial Opportunities Outside the U.S.

Global CGT revenue in 2024

Beyond 50% Ex-US



Big Biopharma Buys In

13 of 15 largest biopharma companies by market cap are investing in the development and/or commercialization of CGT

01 Lilly Market cap = $716 billion	02 novo nordisk Market cap = $384 billion	03 J&J Market cap = $344 billion	04 abbvie Market cap = $309 billion	05 MERCK Market cap = $252 billion
06 Roche Market cap = $234 billion	07 AstraZeneca Market cap = $210 billion	08 NOVARTIS Market cap = $199 billion	09 Pfizer Market cap = $152 billion	10 AMGEN Market cap = $141 billion
11 SANOFI Market cap = $123 billion	12 Bristol Myers Squibb Market cap = $114 billion	13 GILEAD Market cap = $110 billion	14 VERTEX Market cap = $106 billion	15 CSL Market cap = $85 billion

Figures updated as of January 10, 2025

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Source: Alliance for Regenerative Medicine, State of the Industry Address, JPMorgan Healthcare Week

Agenda today

- C&GT industry by the numbers
- C&GT industry by the science
- **Opportunity Australia**

Australia has a well-developed cell therapy delivery ecosystem[1]

Clinical delivery capability

- **138** cell and gene therapy trials to date
- **55** institutions treating patients with cell and gene therapies
- **25** sites approved for commercial CAR-T delivery
- **4** commercial CAR-T products, **7** gene therapies
- Clinical trial costs **25-50%** cheaper than US

Manufacturing and supply chain capability

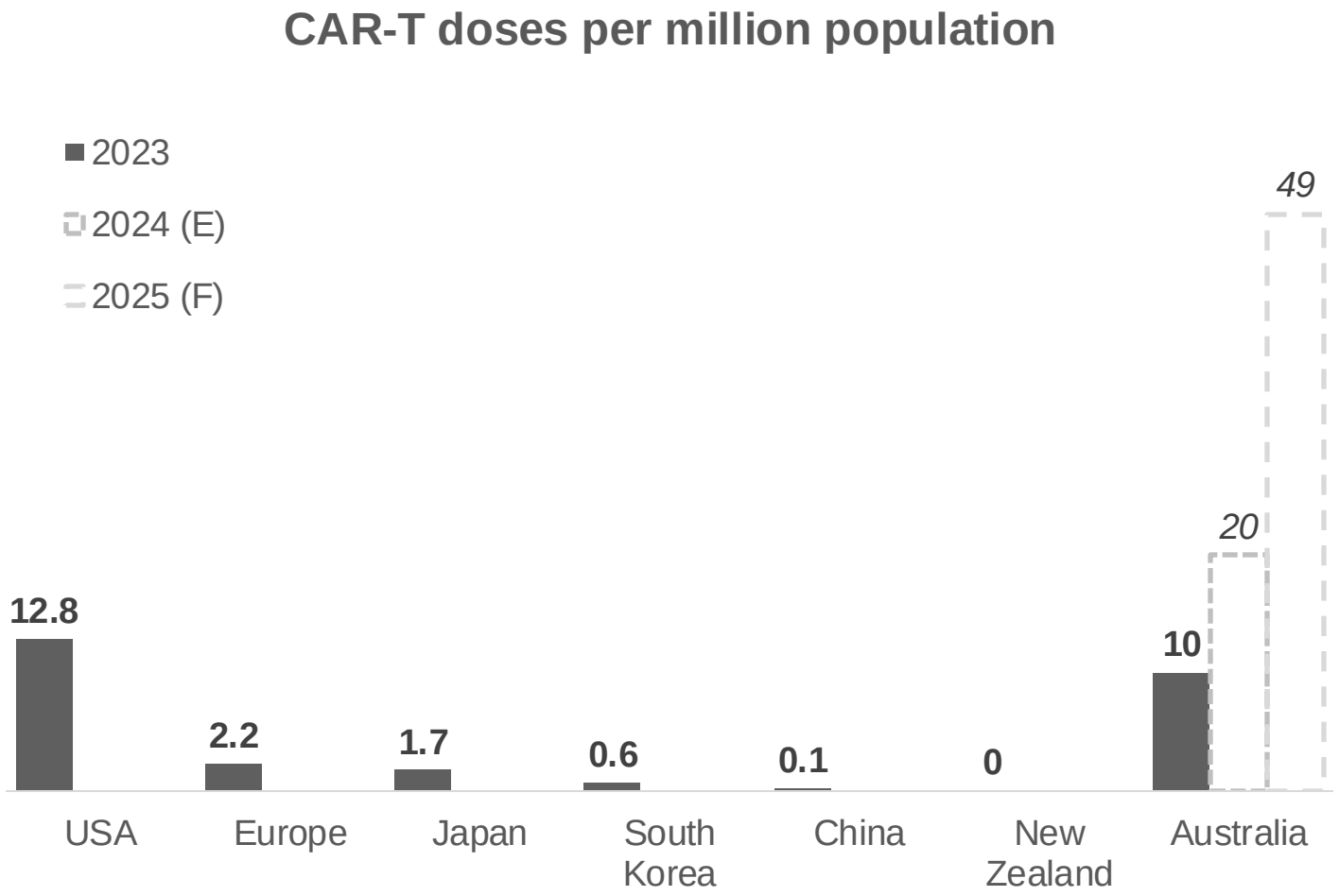
- Several cGMP cell therapy manufacturing facilities
- Cell Therapies Pty Ltd approved for commercial CAR-T supply by TGA and Japan PMDA
- BioOra establishing integrated manufacturing and clinical delivery for NZ and beyond
- Viral Vector Manufacturing Facility Pty Ltd being established
- BioCina Plasmid DNA (vector starting material) CDMO

Innovation and translation

- **>20** companies developing advanced therapeutics
- Cell and Gene Catalyst to drive ecosystem
- R&D Tax Incentive to further leverage cost advantages

1. Adapted from Heather Main, Hoya Consulting (unpublished analysis); company/institution websites

Australian CAR-T penetration is approaching best in world, reinforcing ecosystem strengths



Growth driven by:

- Lymphoma products moving to 2L (2024)
- Assumed financing for myeloma (2025)

Source: AdAlta analysis of variedmarket size, value and pricing reports; Australian estimates via industry survey

Opportunities to strengthen the ecosystem

Strengthen, deepen capital markets

- Clinical stage valuations up to 5-fold higher in US
- Partner sovereign wealth funds with major VC's eg Flagship in Singapore

Sustainable funding pathways

- Certainty, durability, consistency: PBAC or MSAC or High Priced Drugs Scheme

Streamlined regulatory processes

- Orphan designation, provisional review for biologicals (already available for biologic medicines)
- *Ex vivo* CAR-Ts (biological) ineligible for CTN (without FDA IND), but *in vivo* CAR-Ts (biologic medicine) are!
- Post treatment monitoring

Capacity and capability building

- Building skills and capacity systematically across value chain - mRNA model?

National level Advanced Therapies strategy

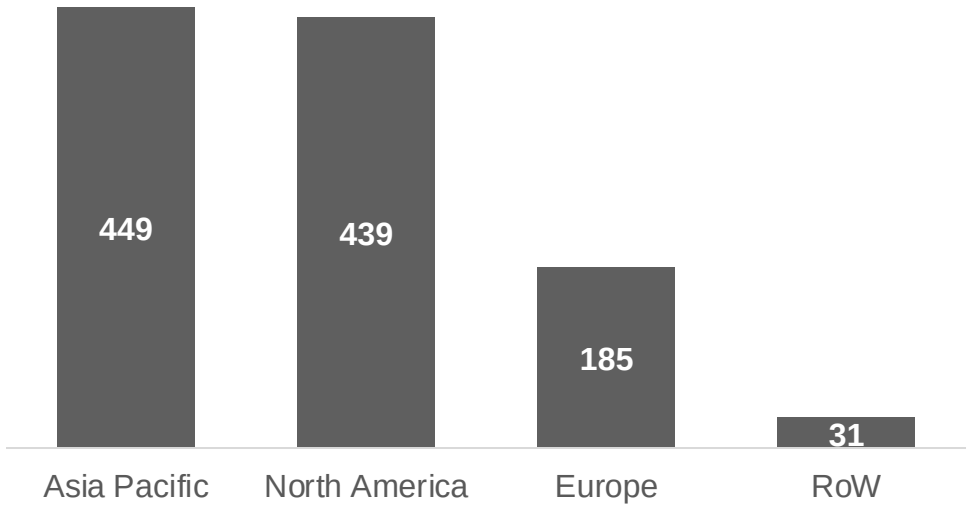
- Integrating Future Made In Australia, NRF, National Health & Medical Research Strategy, and across departments and agencies

Source: valuation analysis by James Tran, adapted from Cell and Gene Catalyst

The rich Eastern hemisphere cellular immunotherapy pipeline is struggling to reach Western markets

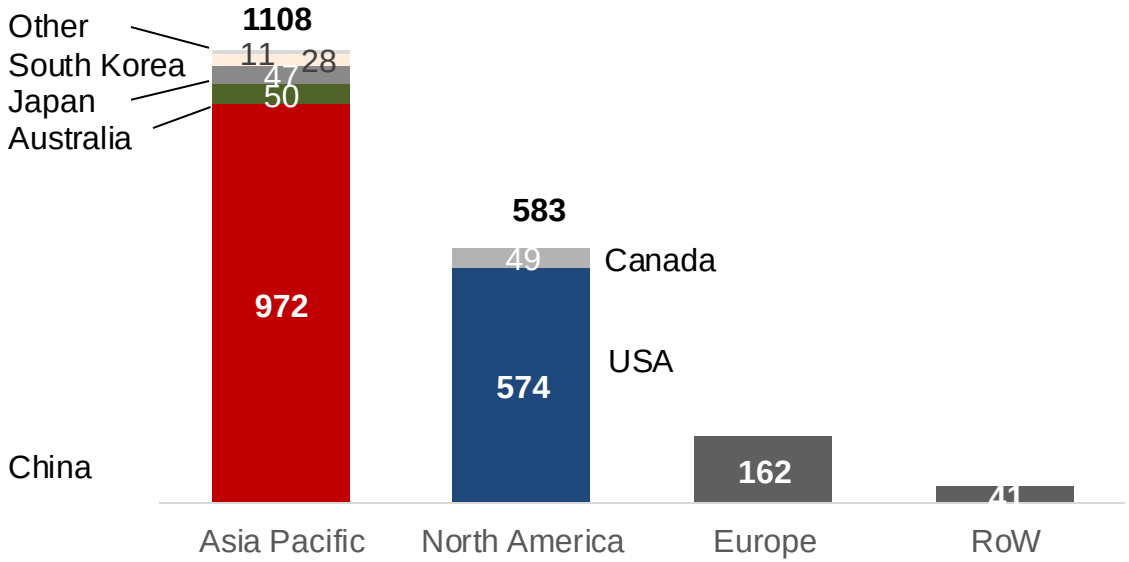
Cellular immunotherapy developers 2023[1]

n = 1,104



Cellular immunotherapy clinical trials 2024[2]

n = 1804



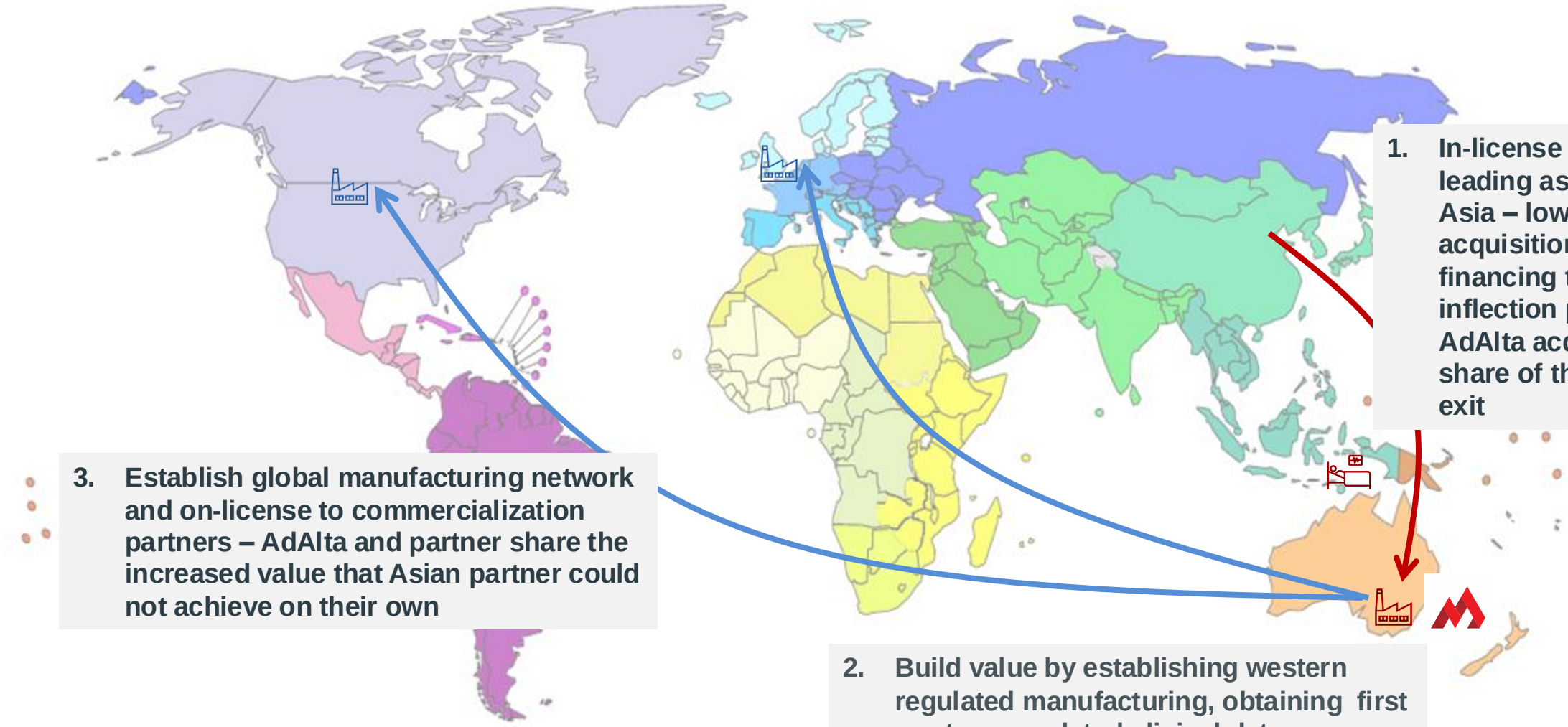
If you attended JPM Week, you couldn't miss it: the biopharma innovation emerging from China and Asia was the topic of conversation. From in-licensing to newcos, deals are closing every week — reshaping the global biopharma landscape. *BioCentury, 23 January 2025*

This year's China story is going to be about the explosion of high-quality, fast-follow assets that are being picked up by richly-funded startup consolidators and by pharma companies hunting for better deals. It's a trend that has the potential to upend the venture capital investment thesis and how we value innovation. *Drew Armstrong, Endpoints News, 10 January 2025*

Lack of capital, experience, networks and ethically diverse data plus geopolitical challenges are hampering flow of innovation from Asia to FDA and EMA regulated markets

1. Alliance for Regenerative Medicine, Developer Data Report Q3 2023. Includes all companies developing gene modified cell therapies and cell-based immuno-oncology products by headquarter region
2. GlobalData, Pharma Intelligence Centre, Clinical Trials Database (accessed 5 April 2024). Includes all adoptive cell therapies (T cell immunotherapies, NK cell immunotherapies and tumour infiltrating lymphocytes. Includes all ongoing clinical trials. Multinational trials are included in each country in which they are conducted

AdAlta's solution and business model: be a force multiplier for Asian partners



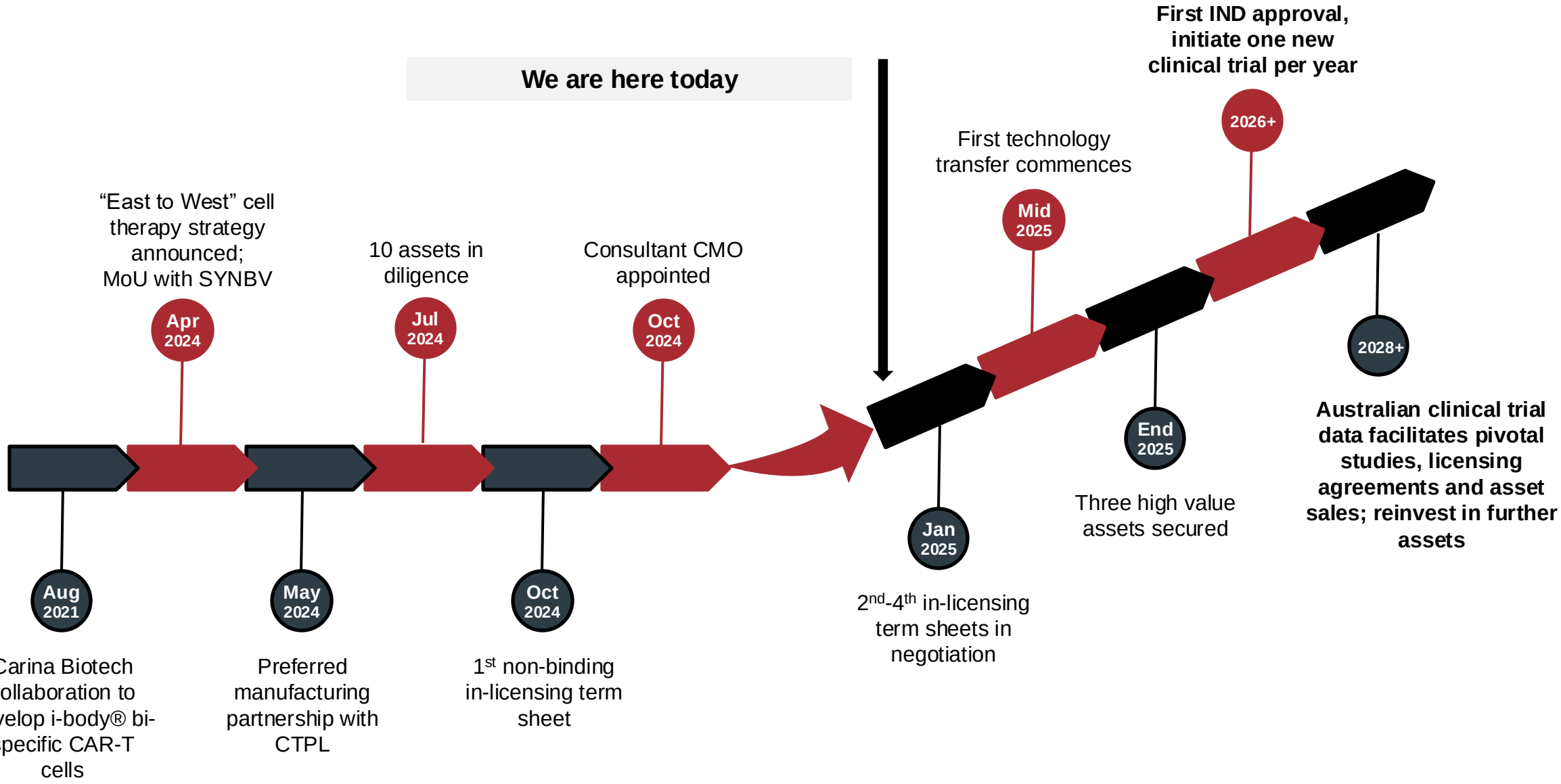
1. In-license market leading assets from Asia – low acquisition cost; by financing to next inflection point AdAlta acquires a share of the asset at exit

2. Build value by establishing western regulated manufacturing, obtaining first western regulated clinical data – substantial inflection and derisking point for big pharma

3. Establish global manufacturing network and on-license to commercialization partners – AdAlta and partner share the increased value that Asian partner could not achieve on their own

Source: F Bray et al, Global cancer statistics 2022: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries, *CA Cancer J Clin* 2024:1-35. doi:10.3322/caac.21834

Progress, potential and ask



Conclusions

The global cell and gene therapy industry continues to advance and grow. The treatment modality is on the cusp of becoming “mainstream”

Asia, particularly China, is driving growth and is a centre of global innovation, but investment to fully realise its potential lags North America

ANZ is a known, material contributor to global innovation and has an excellent foundation for growth, but, like the rest of Asia, would benefit from deeper capital pools

Uniquely, if we are bold enough to build on the platform we have built so far, ANZ is well placed to provide a bridge between Asian innovation and global markets

AdAlta

A modern targeting system for next generation drugs

AdAlta Ltd (ASX:1AD)

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