



**Prescient**  
Therapeutics

**2024 AGM presentation**

**ASX: PTX**

**FASTEST**

**PATH TO**

**MARKET**

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# Chair Address

# Snapshot of 2024 Accomplishments

## PTX-100

- Encouraging data continues to unfold
- Generating awareness amongst KOLs at key global conferences
- Planning and preparation for Phase 2 in CTCL



## CellPryme

- Pre-clinical work largely concluded
- Compelling body of data demonstrating ability to enhance cell therapies
- Partner engagement progressing

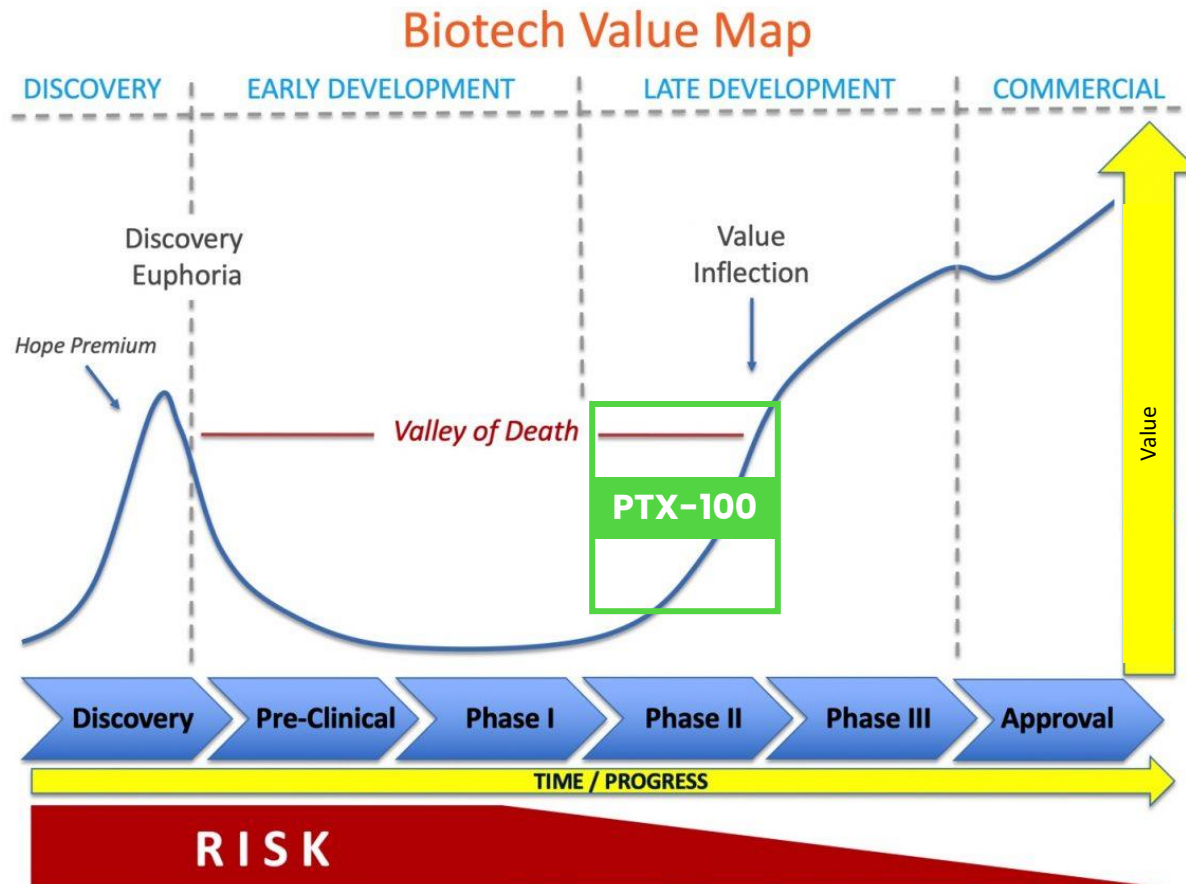


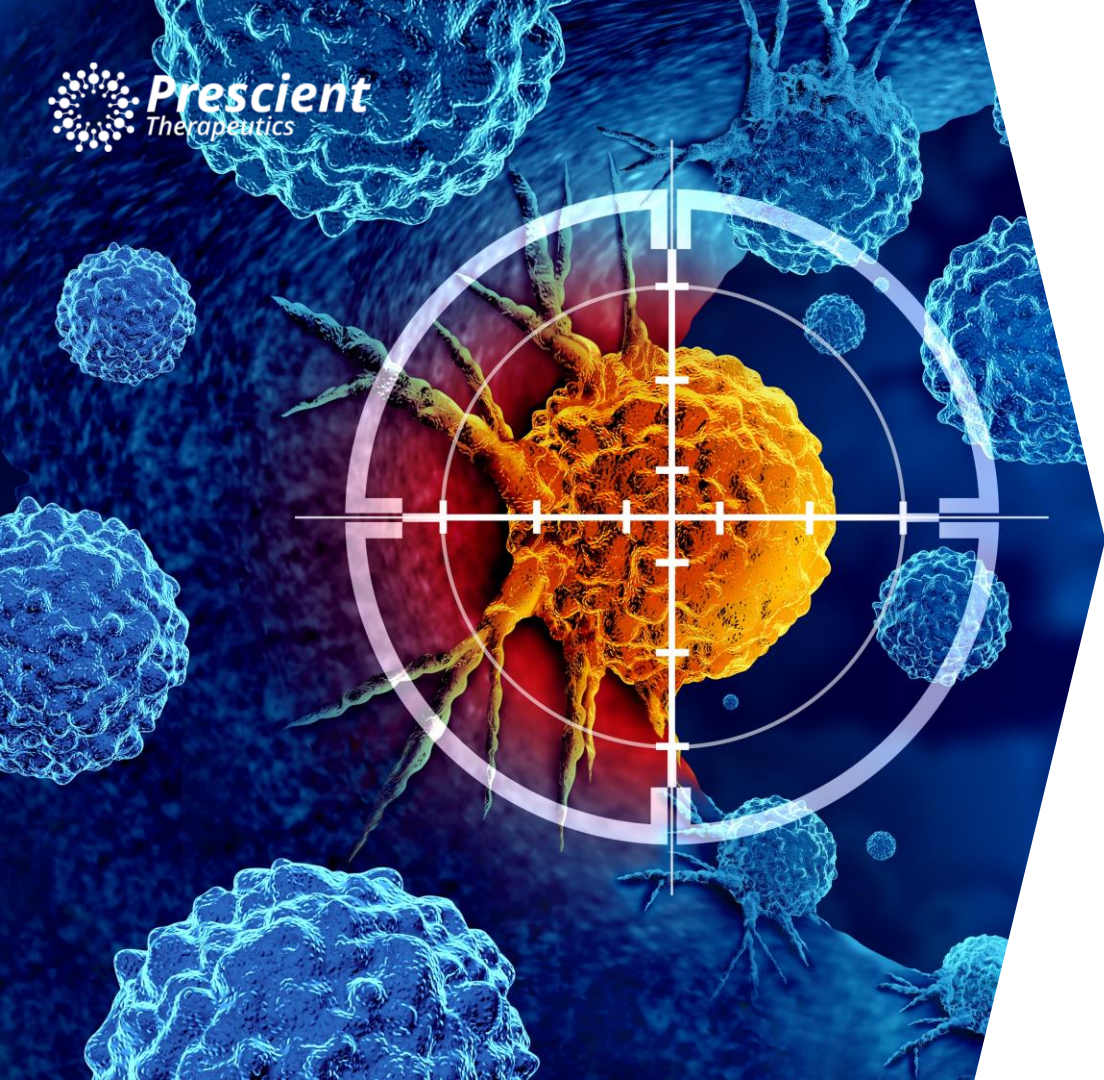
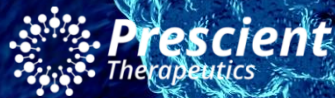
## OmniCAR

- Troubleshooting and problem solving for tonic signalling of unarmed cells
- Very complicated challenge requiring multi-disciplinary effort

- Prudent managing of company resources and awareness building amidst a prolonged challenging biotech market
- Staffing changes to reflect requirements of Prescient's activities and stage of development

# PTX is entering a major inflection point





# PTX-100

## 1ST IN CLASS TARGETED THERAPY



Yale University



# What we've been doing in 2024

- Phase 1b trial ongoing, 25 enrolled with one patient still on therapy. Following safety, responses to treatment and duration of responses.
- PK analysis provides insights into dose levels and dosing schedules
- Presenting data and networking at specialist international forums
  - Building awareness with global key opinion leaders and companies
  - Gathering valuable feedback and insights
- Consulting with regulatory experts regarding development strategy and trial design
- Submitted pre-IND questions to US FDA; working with FDA to identify optimal trial design
- Undertaking chemistry, manufacturing & control activities to support the upcoming PTX-100 trial
  - CMC activities required for registration studies are substantially more thorough and stringent than for earlier clinical studies

# PTX-100 strategy focussing on speed to market

- Prescient will focus its upcoming Phase 2 trial on **relapsed and refractory CTCL**
  - Faster, smaller trial than broader TCL trial
  - Addresses more urgent medical need with less competition
- Aiming for IND allowance by end year and open trial in Q1 2025
- Strategy is to **seek approval for CTCL first**, then **leverage this for separate PTCL registration study**
- In meantime, current Ph1b protocol can be expanded to add more PTCL patients
- Optimal dose of PTX-100 determined in CTCL Ph2 trial can be used in PTCL Ph2 trial
- Development plan more efficient and streamlined
- Subsequent opportunities to study beneficial combinations of PTX-100 with existing agents in CTCL and/or PTCL

## CTCL

- **Higher confidence** of PTX-100 in CTCL (more data; more responders)
- **Greater need** for new therapies (largely ignored)
- Likely to **recruit faster** than PTCL because of lack of trial competition
- **Larger patient pool** because of high prevalence/longer patient life expectancy
- Expected **smaller, faster, cheaper trial design**

## PTCL

- PTCL is more prevalent than CTCL, but even though PTCL is still an unmet need, it has more existing and emerging competition
- PTCL more likely to require larger, more expensive studies that may require a comparator arm
- Use current Ph1b trial to gain more experience with PTCL; upon success, move forward with CTCL optimal dose

# What is Cutaneous T-cell Lymphomas (CTCL)?

- A rare type of cancer of white blood cells (T cells), normally involved in immune function.
- These cancerous T cells travel to and live in the skin, where they grow and divide uncontrollably, attacking the skin.
- CTCLs include group of subtypes, most commonly Mycosis Fungoides and Sezary Syndrome
- Can be indolent or aggressive, and range from rash-like patches through to plaques and tumours
- Limited options for patients with relapsed or refractory CTCL
- Orphan disease: 1000 new cases in US each year and increasing
- Market projected to grow to US\$748M by 2032



# Relevant CTCL case study



- Fusion protein of IL-2 and diphtheria toxin, developed by Citius and Dr Reddy's
  - Purer version of Eisai's Ontak (withdrawn from market in 2014 due to manufacturing issues)
- Approved in US August 2024 for patients with CD25+ r/rCTCL
- Estimated cost of US\$200,000 per patient, per year

## Lymphir Registration trial results:

- **ORR: 36%**
- Median duration of response: **6.5 months**
- Safety: adverse events in 98.6% of patients, of which **38% were serious**

# PTX-100

## Phase 1b study

# PTX-100: Ph1b Clinical Summary

- **Aims:** Phase 1b to evaluate safety PK/PD
- **Design:** Dose escalation in advanced malignancies; expansion cohort (n=25) in relapsed & refractory T cell lymphomas
- **Results:**
  - Excellent safety
  - Target engagement at all 3 doses
  - **Response rates (incl 3 CRs) in assessable pts exceeding SoC threshold (30% ORR) to advance program**
- **Granted Orphan Drug Designation by US FDA for all TCLs**



Professor H. Miles Prince, AM  
Principal Investigator



# Drugs for relapsed/refractory TCL can be judged on 3 criteria:

## Expected



Serious Adverse Events  
>30% of the time



~30%  
patients respond



For those who respond:  
CTCL: 9-13 months  
PTCL: 3-4 months



† Expected DoR 3-4 months for PTCL; 9-13 months for CTCL

# PTX-100 stacks up favourably against all benchmark TCL criteria:

## Expected

## PTX-100



Serious Adverse Events  
>30% of the time



~30%  
patients respond



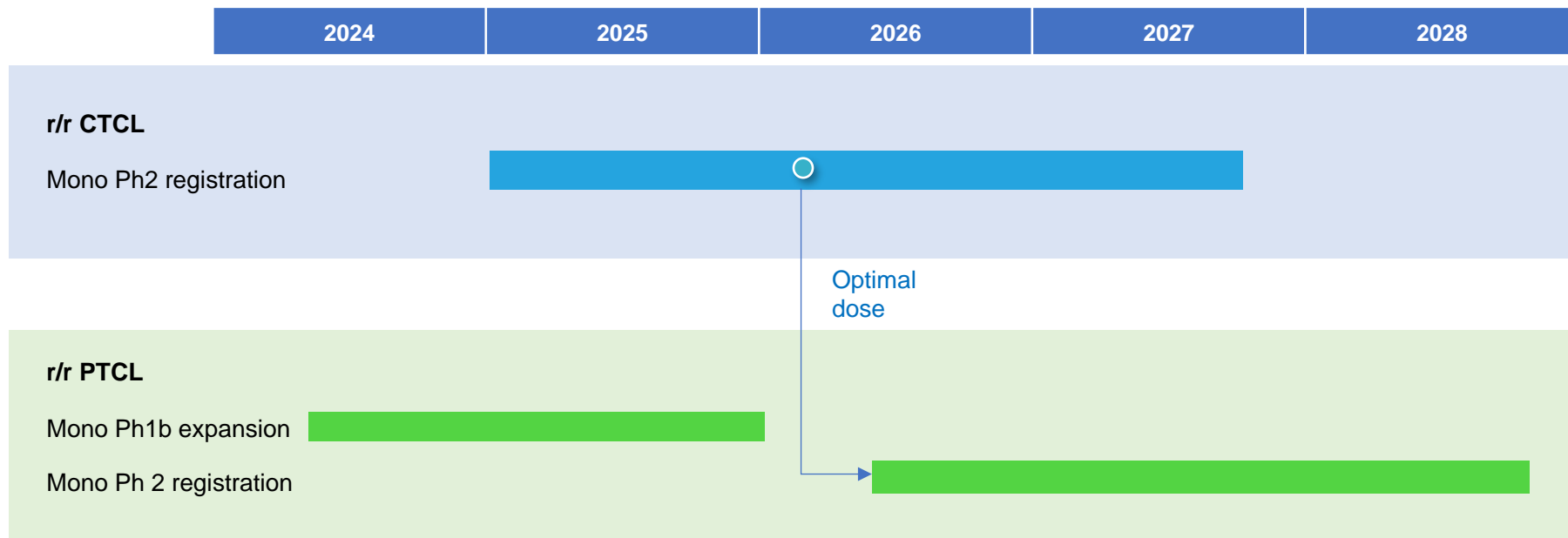
For those who respond:  
CTCL: 9-13 months  
PTCL: 3-4 months



# PTX-100 Phase 2 trial status

- In dialogue with US FDA. Areas of focus
  - Dose optimization ( a requirement for all companies as per Project Optimus)
  - Non-clinical data on drug-drug interactions
  - These are readily addressable
- On track for IND submission imminently
- IND allowance will allow trial to start
- Appointment of key vendors (e.g. clinical CROs, EDCs, regulatory, stats) following extensive RFPs and interviews to find most appropriate vendors at best prices
- CMC campaign has been very active in parallel with vendors appointed, activities underway, and bolstering in-house CMC expertise

# Potential PTX-100 development plan



NB: Does not take into account the additional opportunities of combining PTX-100 with existing therapies

## Progress

- Phase 1b data continued to impress
- Presentation at global hem-onc conferences
- Recruited support of KOLs
- Refined design and plan with valuable input from KOLs and regulatory experts
- FDA interactions in preparation for new IND
- Huge clinical planning and CMC effort

## Challenges

- Recruitment for rare diseases
- CMC campaign ongoing – big jump from Ph1 to registration standard
- Goes beyond actual manufacturing and includes parallel, ongoing validation
- Project Optimus dose optimisation requirements

## Going forward

- IND submission and protocol finalisation (imminent)
- IND and protocol allowance by FDA
- Phase 2 trial open in CTCL
- Expansion into overseas sites
- Build experience in PTCL under current Ph1b protocol
- Seek strategic value-adding alliances

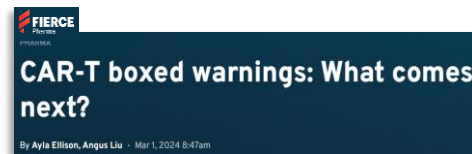
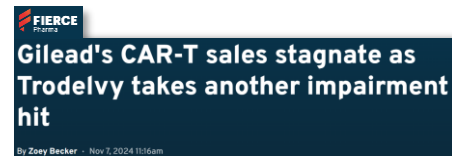


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# CELL THERAPY PLATFORMS

# Challenges for the Cell Therapy sector

- Still largely in malaise; expensive to research and develop in a capital-constrained environment
- Most CAR-T therapies that have been approved have still not resulted in profitability
- Boxed warnings for CAR-T in early 2024
- Manufacturing and logistics issues are limiting roll-out; hospital capacity also a constraint
- Has discouraged investment into many earlier stage cell therapy programs
- Despite sector severely cutting back pipelines, there is still a large amount of overlap
  - Many CD19 CAR-T programs have pivoted to autoimmunity in an attempt to differentiate
- Progress and success of allogeneic cells are lagging
- Competition from next-gen T-cell engagers (e.g. Amgen's tarlatamab for small cell lung cancer, approved May 2024) and potential disruption from *in vivo* cell therapies



# A reminder that Prescient has deliberately positioned itself to be a 3<sup>rd</sup> party problem solver for cell therapy challenges



Safety & Control



-



Targeting



-



Escape



-



Production efficiency



-



Exhaustion



Trafficking



Tumor penetrance



Tumor microenvironment



**Safer**

**More  
effective**

**Accessible &  
affordable**

# PTX strategically positioned in an evolving field

## Current generation CAR-Ts



Emerging immune cell types



Manufacturing methods



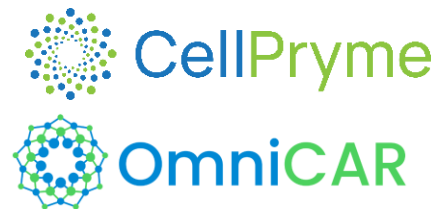
Emerging targets



Other cancers



Beyond oncology



Can enhance existing and emerging cell therapies

Other cell therapy companies are **potential customers, not competitors**



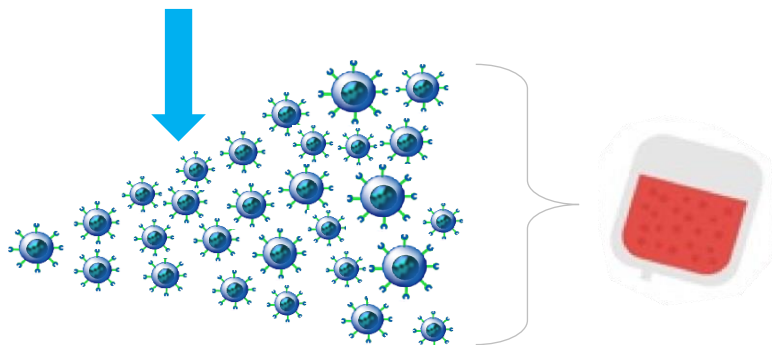
CellPryme

**CELL THERAPY  
ENHANCEMENTS**

# CellPryme: enhancing cell therapies in two ways



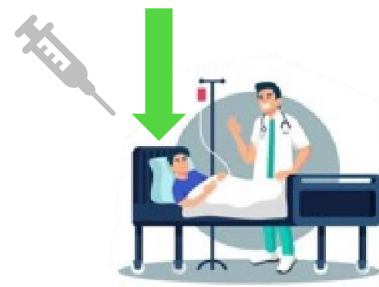
**MANUFACTURING ENHANCEMENT**



**Non-disruptive additive  
during cell manufacturing**



**ADJUVANT THERAPY**



**Administered to patient  
concurrent with cell therapy**

## Progress

- Pre-clinical studies largely concluded, reinforcing very encouraging results
- PMCC finalising research involving crucial interaction with the tumour microenvironment (TME)
- Presentation at global conferences
- DD and testing underway with several potential partners for CellPryme-M
  - Requires close collaboration to test with their own processes and/or alongside their own proprietary products

## Challenges

- Third parties (particularly for CellPryme-A) having severe financing constraints that are a big barrier to new programs

## Going forward

- Publication of final data that includes new data on how CellPryme interacts with the TME
- Progress due diligence and testing activities with potential partners, working towards a commercial agreement for CellPryme-M (ideally a channel partner)
- Seek create avenues for FIH clinical trial of CellPryme-A
- CellPryme-A in particular can have applications in new emerging area of cell therapy and immunotherapy (lower redundancy risk)



# OmniCAR

**Universal, Next-Gen cell therapies**

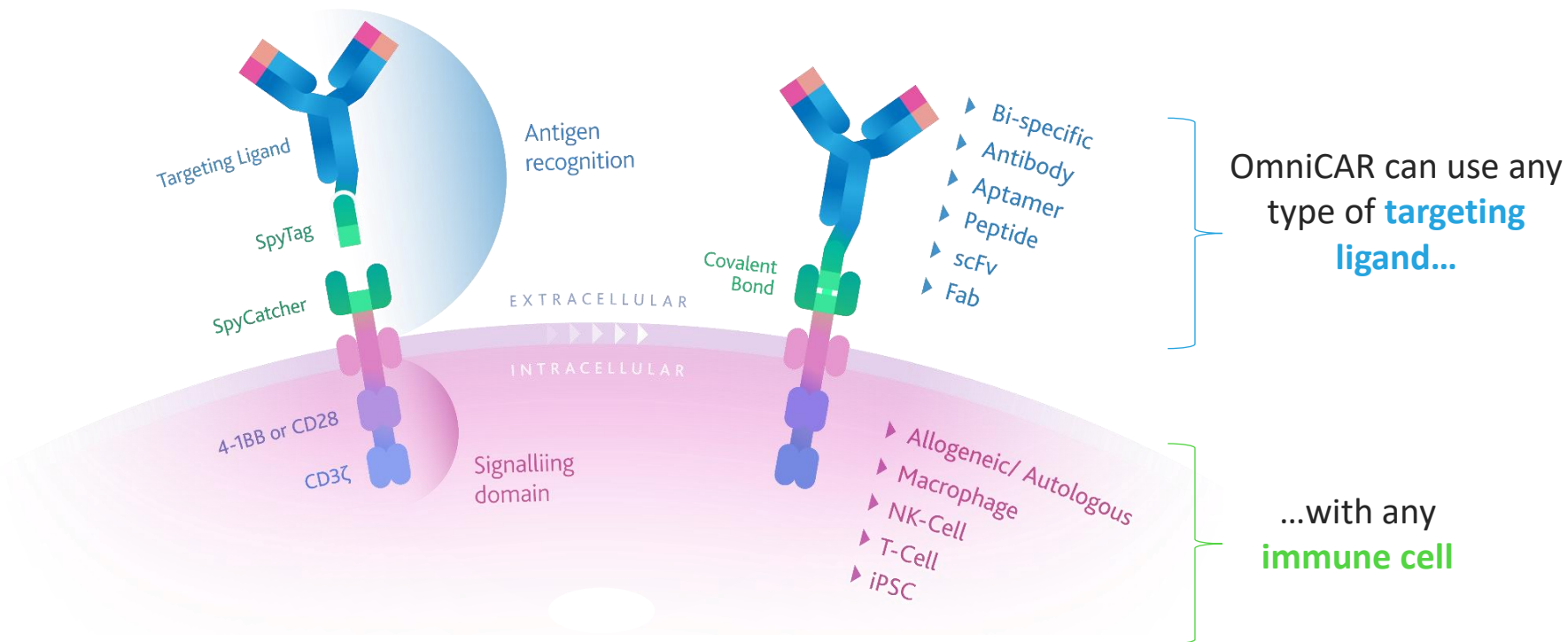


**Penn**  
UNIVERSITY of PENNSYLVANIA



UNIVERSITY OF  
**OXFORD**

# Any immune cell → to any target



## Progress

- PTX team has been addressing cytotoxicity of unarmed OmniCAR cells. This is essential for clinical development
- Development effort to try to address the issue has been underway throughout 2024. Involves PTX team; Peter Mac & CSIRO across multiple disciplines including cell biology; protein engineering and bioinformatics.
- Many new OmniCAR variants designed, created and tested
- Development effort is on time and on budget

## Challenges

- A hugely complex and multi-faceted, multi-disciplinary problem, with no guarantee of a successful outcome
- Cell therapy malaise is ongoing
- Third parties having severe financing constraints that are a big barrier to new programs – especially those programs that require complete redesign of constructs
- Emerging modalities like in vivo may revolutionise cell therapy, and might address some of the problems that modularity is seeking to address

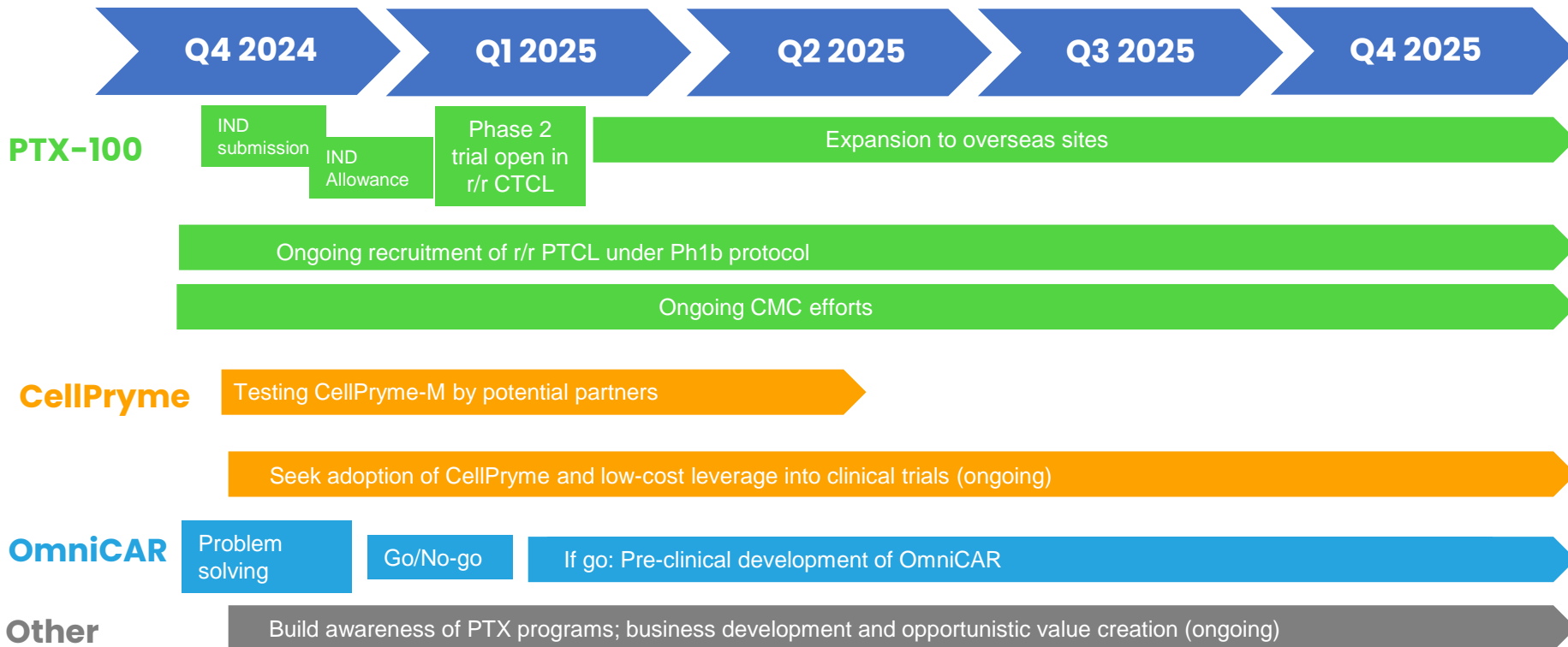
## Going forward

- Conclusion of problem-solving activities to identify OmniCAR v2.0
- Go/no-go determination
- If decide to proceed, review the OmniCAR development plan in light of tech advances and evolution of the cell therapy field
- Despite technological advances, PTX still believes that modularity can play a key role in the future of cell therapy

# Summary

# Major catalysts to work towards next year

Prescient will continue to progress the development of programs across its pipeline. Some notable catalysts to work towards include, but are not limited to:

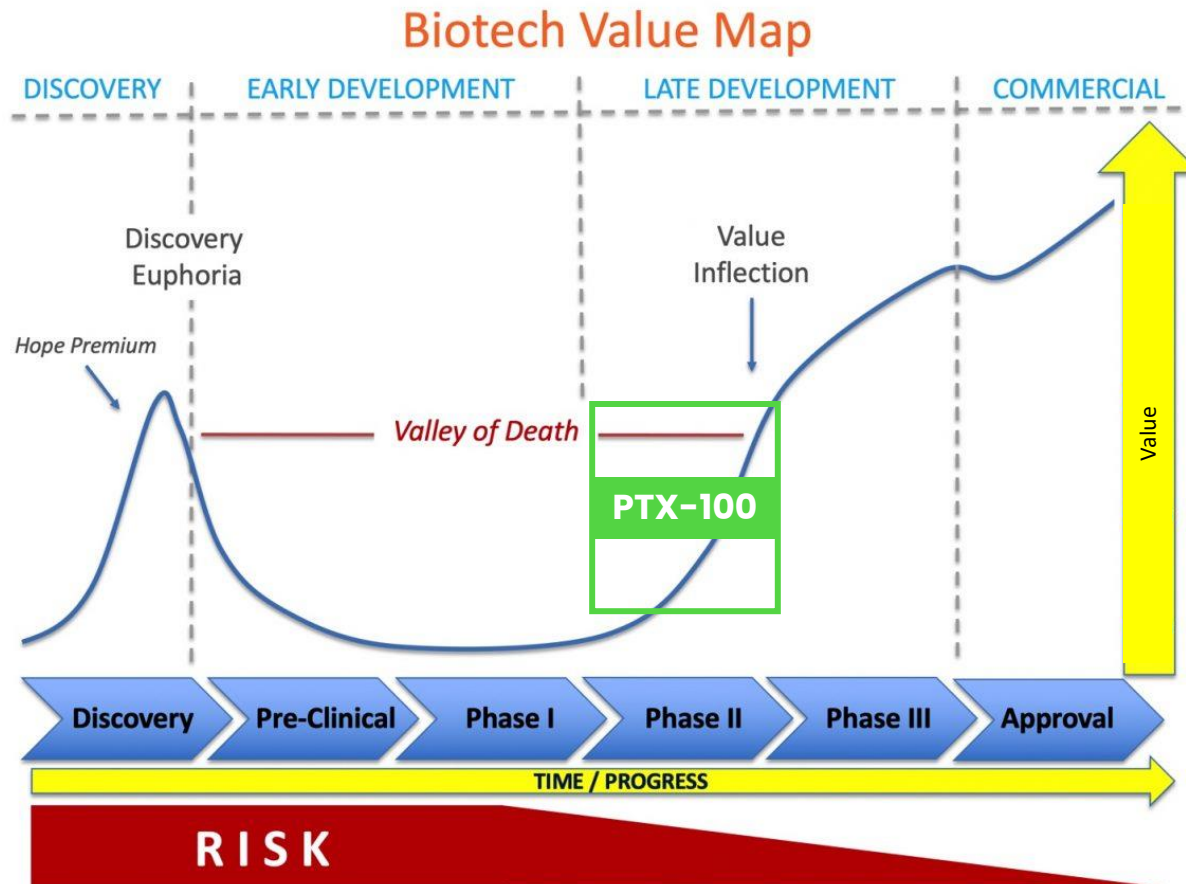


# Aspirations for each program in 5 years if they succeed

**Not everything will go to plan, but any one of these successes could be transformative for PTX**

- PTX-100
  - Approved in r/r CTCL, with product sales
  - Registration study for r/r PTCL
  - In additional Phase 2 trials to dominate TCL:
    - Combination therapies
    - Earlier lines of therapy
    - Indications beyond TCL
  - New formulations to extend IP and broaden applications
- CellPryme
  - CellPryme-M generating modest but recurring revenues from a number of biotech and CDMO partners
  - CellPryme-A with 1st approval in combination with CAR-T and undergoing additional clinical trials for approvals with other CAR-T products
- OmniCAR
  - >1 Internal program in Ph1/2 trial
  - 3-4 External programs in clinical development, more in pre-clinical development
- Portfolio expansion in areas of expertise

# PTX is entering a major inflection point





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**THANK  
YOU**

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