



# A YEAR OF TRANSFORMATION

Annual General Meeting

November 2020



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# Executive Summary

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- Year of transformation
- Navigating challenges & uncertainty of COVID-19
- Progression of PTX-200 in AML
- Encouraging data from PTX-100 study in a very hot area (Ras)
- Leveraging expertise into new fields to create new value-adding opportunities – Cell Therapy Enhancements and COVID-19
- Transformative licenses from UPenn and Oxford to create OmniCAR platform for next-gen CAR-T
- Catapults PTX to the forefront of CAR-T innovation
- Drug development and CAR-T expert Dr Allen Ebens joins Board
- Oversubscribed capital raising attracted new sophisticated investors

# An Expanded & Innovative Pipeline



CAR - T

DISCOVERY      SCREENING      PRECLINICAL      PHASE 1      PHASE 1B      PHASE 2      PHASE 3

OMNICAR  
PLATFORM

Next Generation Universal CARs

CELL THERAPY  
ENHANCEMENTS

Undisclosed 1



CELL THERAPY  
ENHANCEMENTS

Undisclosed 2



PTX - 100

Ras & Rho Basket Study



TARGETED  
THERAPIES

PTX - 200

AML

PTX - 200

Breast Cancer (pivoting to new combination in ER+ disease)

PTX - 200

Ovarian Cancer (pivoting to new combination)

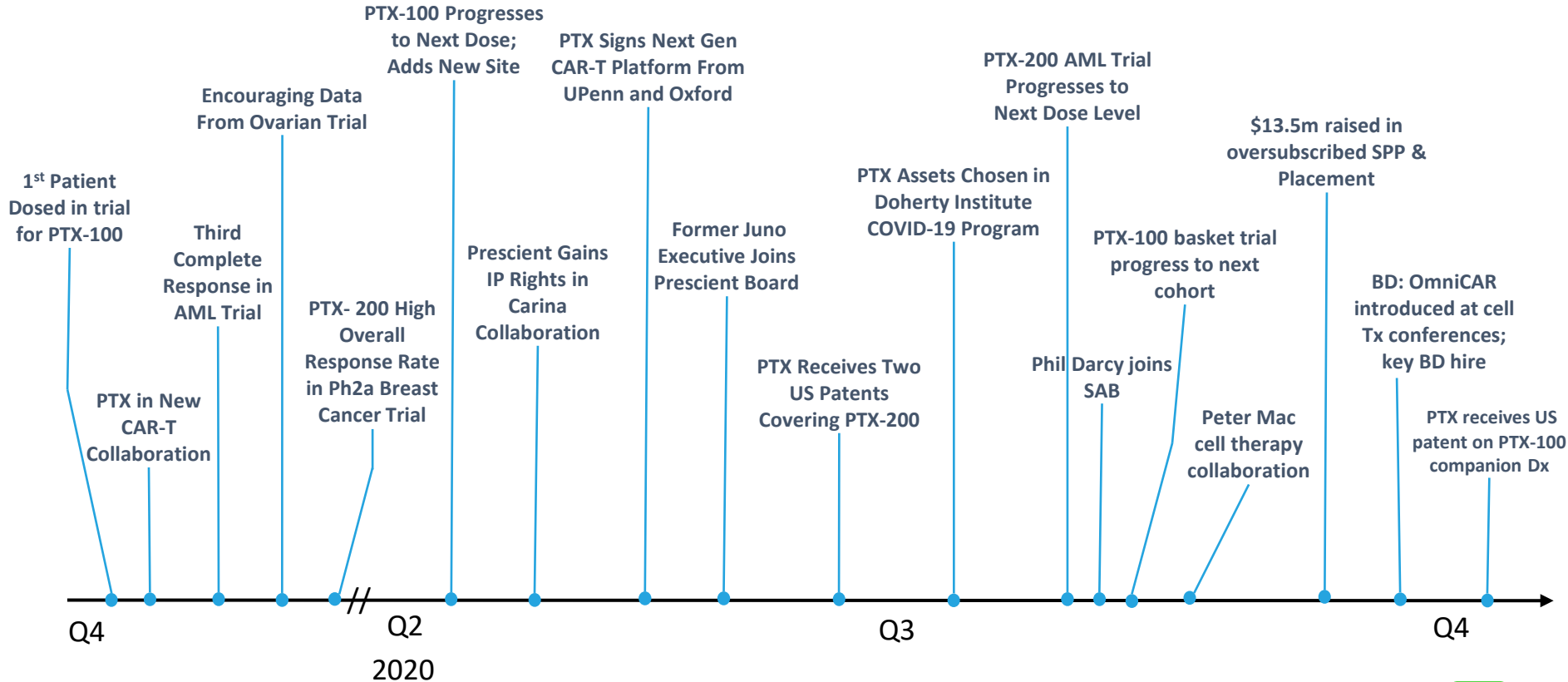


COVID-19

UNDISCLOSED 1

UNDISCLOSED 2

# A productive 12 months yielding many achievements



## COVID-19



- No specific and material disruptions, but impossible to escape its impact
- Patients still enrolling, but slower
- Lockdowns and restrictions impacted research institutes – preclinical & clinical lab work
- US pandemic is worsening (risks impacting preclinical and clinical work)

## PTX-100 trial – a great “problem” to have!



- Patients are staying on therapy much longer (and at earlier cohorts) than we anticipated
- Requires manufacturing additional PTX-100 and managing patient enrolment
- May push study dates out, but for a good reason!

## Travel & Conferences



- Industry has adjusted well to virtual conferences, but these interactions have their limitations
- PTX has hired Dr Dan Shelly as VP – BD & Alliances, based in US to address increased BD activity & travel limitations

# PTX-100

FIRST IN CLASS, FIRST IN MAN  
GGT-1 INHIBITOR OF RAS PATHWAY

## First in Class inhibitor of Ras pathway

- Downstream MoA captures **many Ras mutant variants**
- PTX-100 is only RhoA inhibitor in clinical development
- Reduces cancer stem cells

## Clinical Status

- Phase 1 advanced solid tumor complete (safe; clinical activity)
- Phase 1b PK/PD Basket trial underway
  - heme, solid tumours with Ras and Rho mutations
  - **Clinical signal at first cohort**



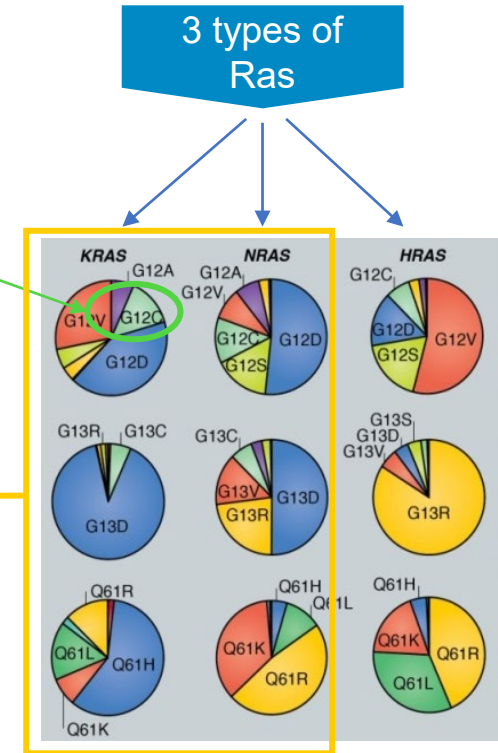
# PTX-100 ADDRESSES MANY TYPES OF RAS MUTATIONS



- 80% of cancer Ras cancer patients harbour **more than one Ras mutation!**
- Competitor drugs are targeting one very specific type of Ras mutation
  - KRAS G12C
  - This approach can lead to **underwhelming responses and/or relapse**
- PTX-100 has a unique mechanism that can potentially address **all K-Ras and N-Ras mutant cancers**

AMGEN  
MIRATI  
THERAPEUTICS

Prescient  
Therapeutics



# PTX-100 PHASE 1B BASKET STUDY UNDERWAY

- Phase 1 trial in solid tumours completed – safety profile established.
- Now focussing on Ras and Rho mutant cancers.
- PTX-100 has a unique position in Ras and RhoA mutant malignancies**
- Phase 1b PK/PD commenced
- Basket trial of:
  - Gastric cancer
  - Pancreatic cancer
  - Colorectal cancer
  - Myeloma
  - T-cell lymphomas
- Clinical signal in first cohort (SD & PR)**
- Patients staying on drug for longer than expected (an encouraging sign)
- Necessitating additional manufacturing of PTX-100 and managing patient enrolment



Professor H. Miles Prince, AM  
Principal Investigator



# PTX-200

NOVEL AKT INHIBITION  
OVERCOMING KINASE PROMISCUITY  
& LIMITATIONS OF PREVIOUS ATTEMPTS AT AKT INHIBITION

## Novel PH Domain & Akt inhibition

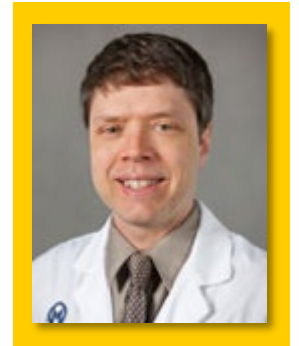
- Unique MoA (not a kinase inhibitor)
- Selectively kills tumors with hyperactivated Akt
- Orphan Drug Designation

## Clinical Status

- Clinical PoC established
- Her2- Breast cancer Ph2a: ORR 91% including 3 CRs. Responses durable. ZNF217 biomarker.
- AML Ph1b: 3 CRs
- Ovarian cancer Ph1b: 80% disease control

## PHASE 1B TRIAL UNDERWAY: ACUTE MYELOID LEUKEMIA

- Building upon encouraging Phase 1 results with PTX-200 (monotherapy)
- PI Professor Jeff Lancet at Moffitt, with Dr Tara Lin at KUMC
- 15 patients with cytarabine held constant at 200-400 mg/m<sup>2</sup> as continuous infusion
  - » 3 CRs so far
- New dosing schedule to minimize overlapping drug interactions
- Currently enrolling second cohort at 35 mg/m<sup>2</sup>
- Granted Orphan Drug Designation by US FDA



Jeffrey E Lancet, M.D.  
Principal Investigator





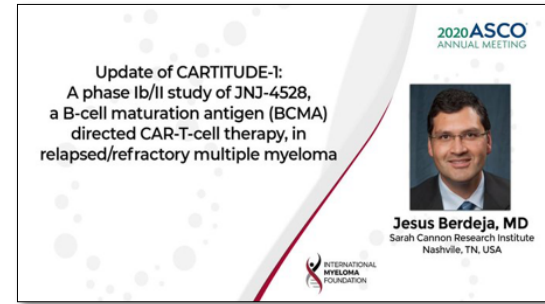
# OmniCAR

Universal, Next Generation CAR-T

# CAR-T: A genuine turning point in cancer treatment

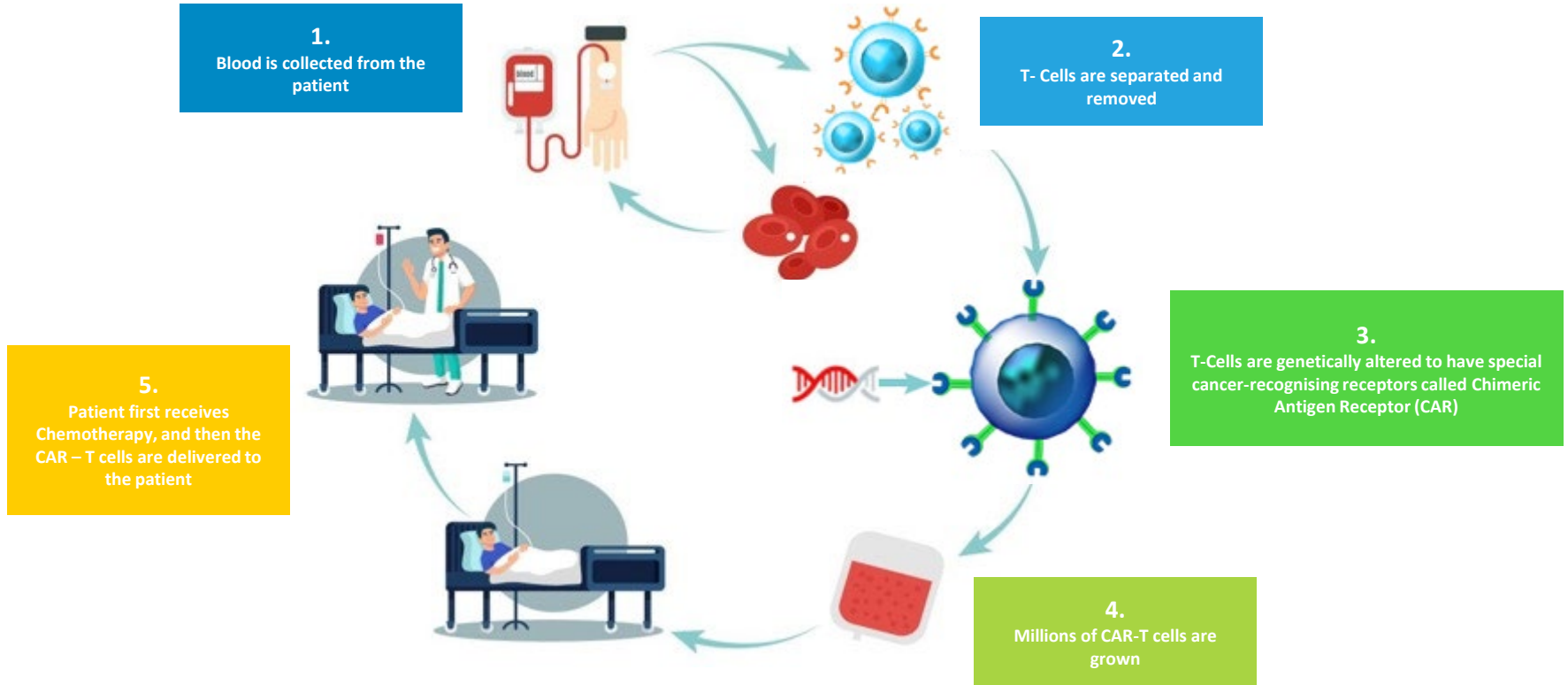
*“CAR T represents a turning point in the history of human medicine, a genuine revolution in our approach to disease.”<sup>1</sup>*

- At ASCO 2020 (June) Johnson & Johnson presented an update on their CAR-T therapy for multiple myeloma
- The overall response rate (ORR) was 100%



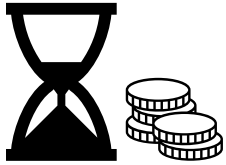
1. CAR-T and The Rise of the Cellicon Valley; UPenn, 2017; <https://www.med.upenn.edu/cart/>

# How does the CAR-T process work?





# Key Challenges Confronting the field of CAR-T



## Time and Cost

of delivering  
treatment



## Safety

CAR-T can have  
serious safety  
concerns



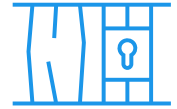
## No Control

Clinicians have no  
control of cells post  
infusion



## Targets

Finding targets that  
work;  
Antigen heterogeneity  
(multiple targets) -  
esp. in solid tumours



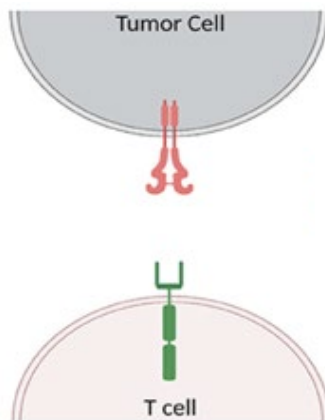
## Escape

Antigen loss  
leads to relapse

# How OmniCAR works

1

Unarmed CAR-T cells are administered to patient  
**viable but inactive**



Unarmed CAR-T

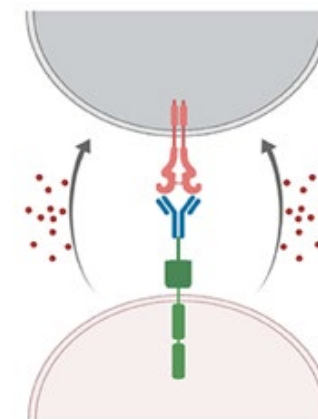
2

Separate administration  
of **targeting ligand**  
results in a complete,  
armed CAR-T cell



3

**Armed CAR-T cells are activated**, resulting in on-demand tumour killing



Armed CAR-T

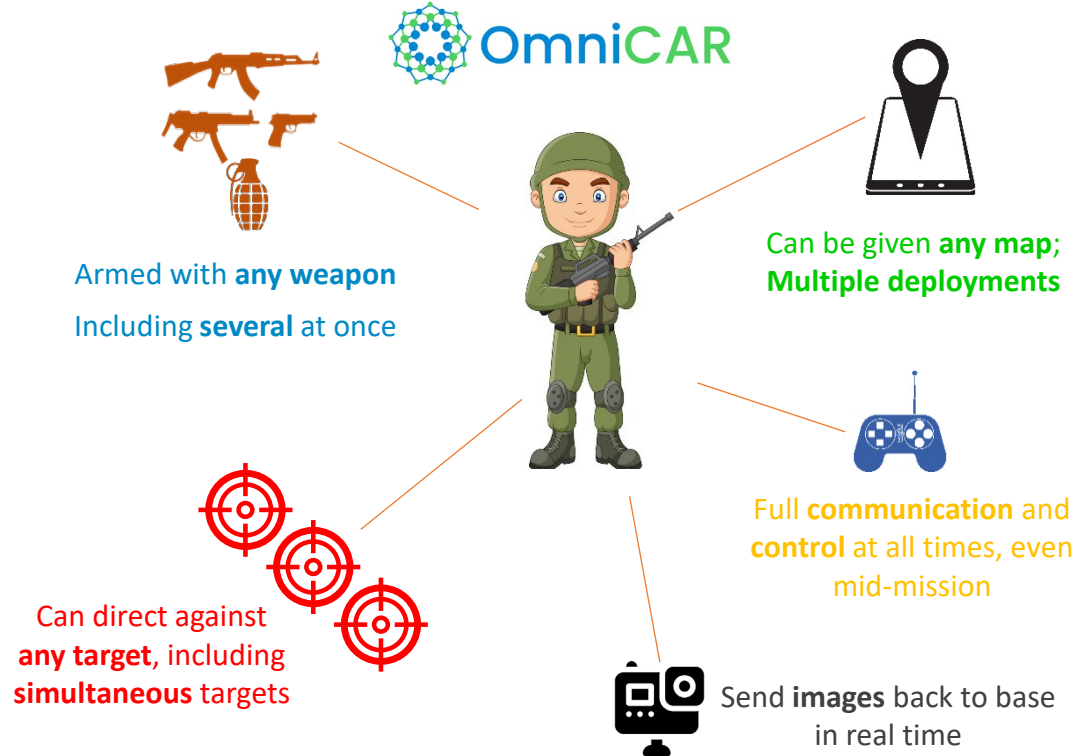
- CAR-T cell activity is **now controllable**
- Targeting can be **switched at will**, by administering a different targeting ligand

# OmniCAR can do what conventional CAR-T cannot

## Conventional CAR-T



- Soldier with only one map
- Single weapon
- Only trained to hit one target
- Incapable of redirection
- No communication or control in the field

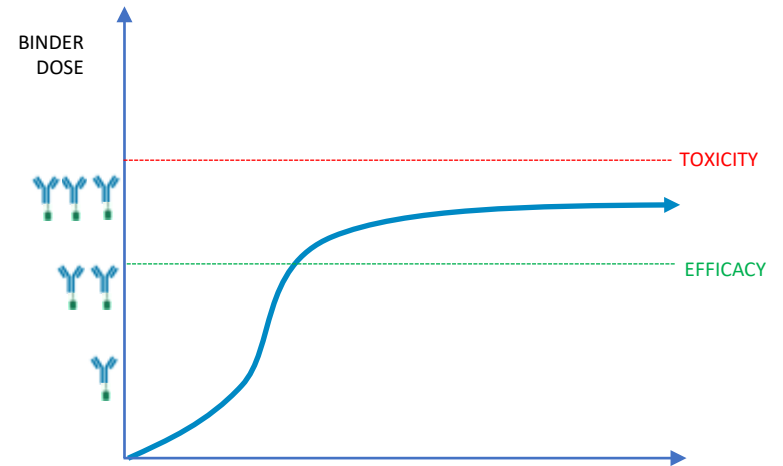
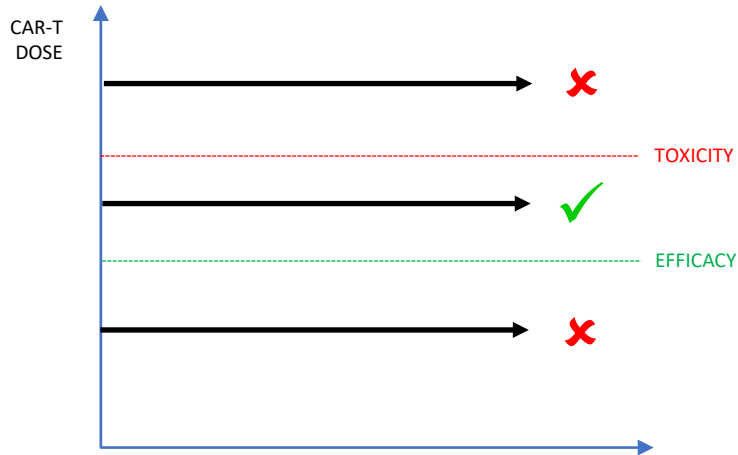


# Overcoming Clinical Limitations of CAR-T

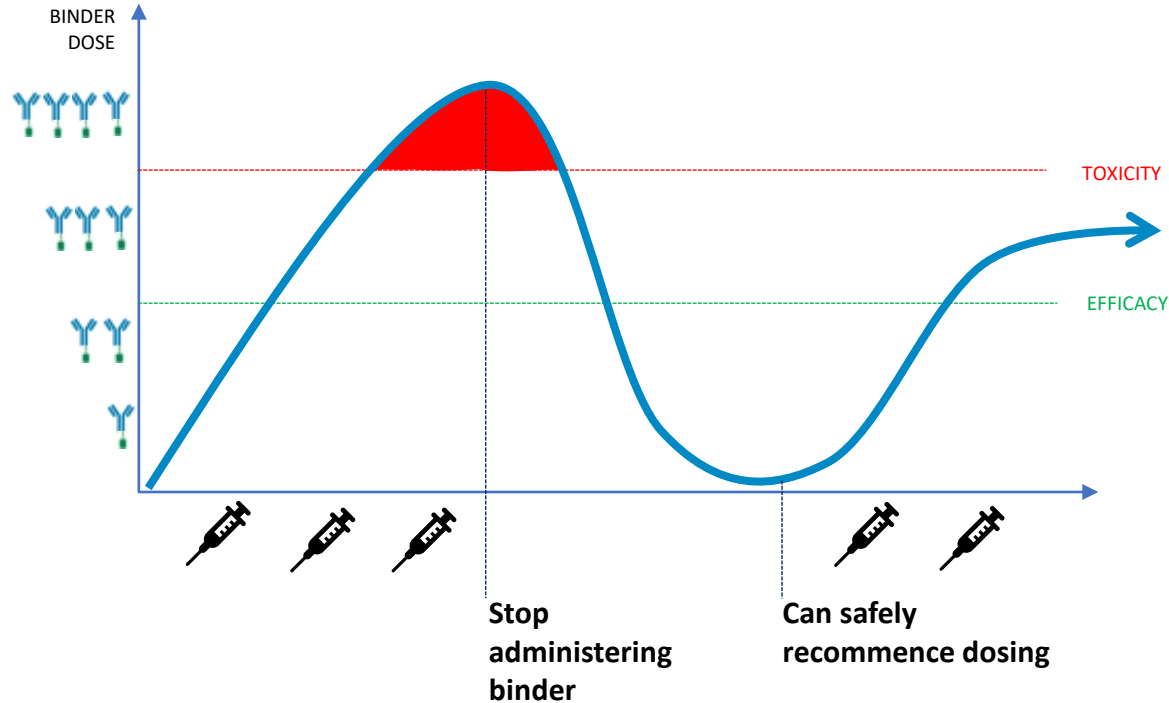
| Clinical Challenges   | Conventional CAR-T                               | Universal CAR-T (OmniCAR)   |
|---|--|---|
| On-demand activation of CAR-T cell                                  | ✗  | ✓   |
| Controlling CAR-T cell activity post infusion                       | ✗  | ✓   |
| Control serious side effects (TLS; CRS)                             | ✗  | ✓<br>(preventative and responsive)  |
| Ability to terminate activity in the event of serious adverse event | ✗  | ✓   |
| Prevention of B-cell aplasia (CD19)                                 | ✗  | ✓<br>(reversible)   |
| Recallable memory response  | ✗  | ✓   |
| Solid tumour targeting  | Off-target tissue activity is a major limitation | ✓<br>Titrate to achieve therapeutic index   |
| Addressing tumour antigen loss                                      | ✗  | ✓   |
| Treatment of heterogeneous tumours                                  | ✗  | ✓   |
| Universal vector design   | ✗  | ✓   |
| Cost of therapy   | High   | Single vector design to reduce cost; can be incorporated into off-the-shelf T cells |

# Safety: Ability Control Dose & Activity

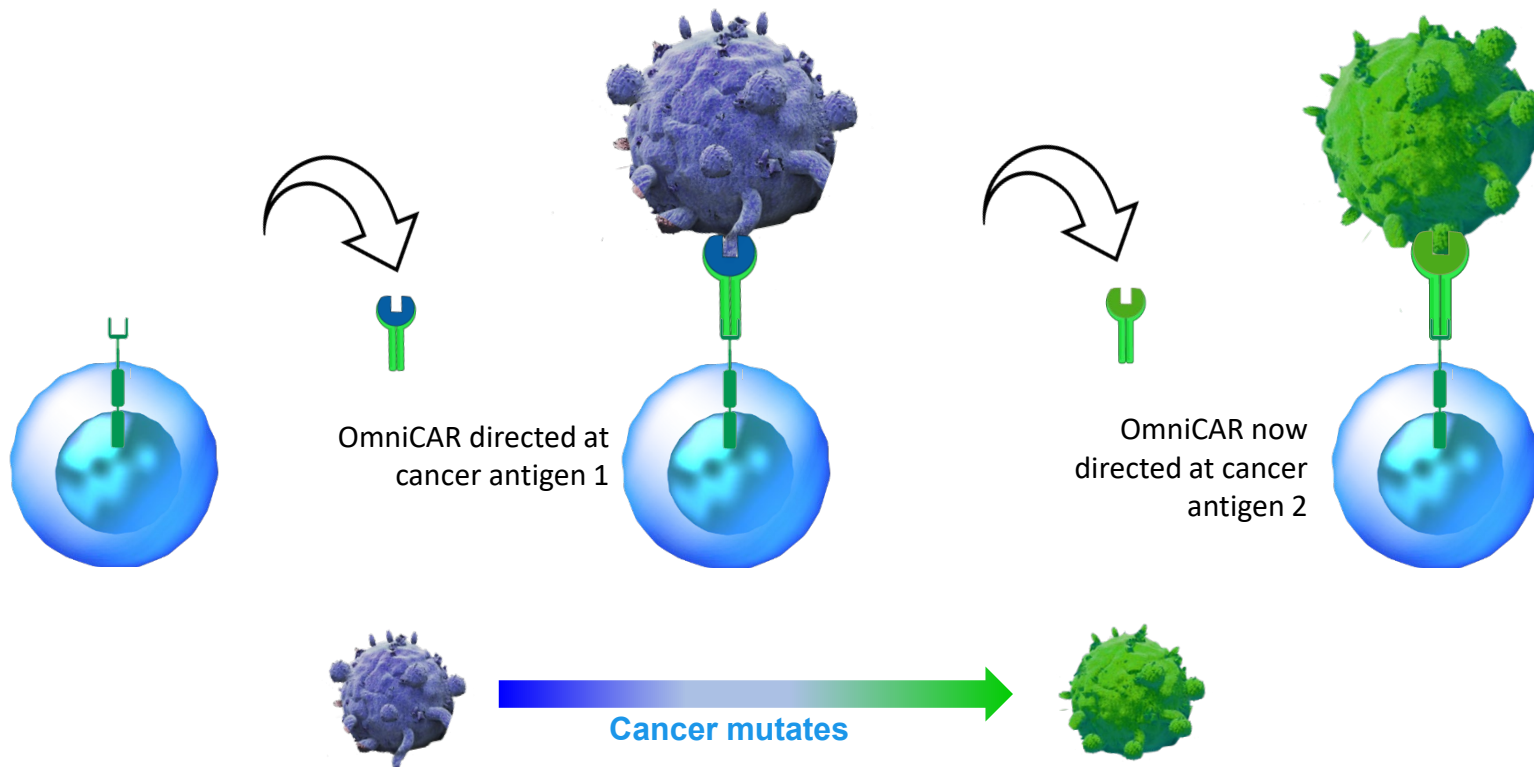
## Conventional CAR-T



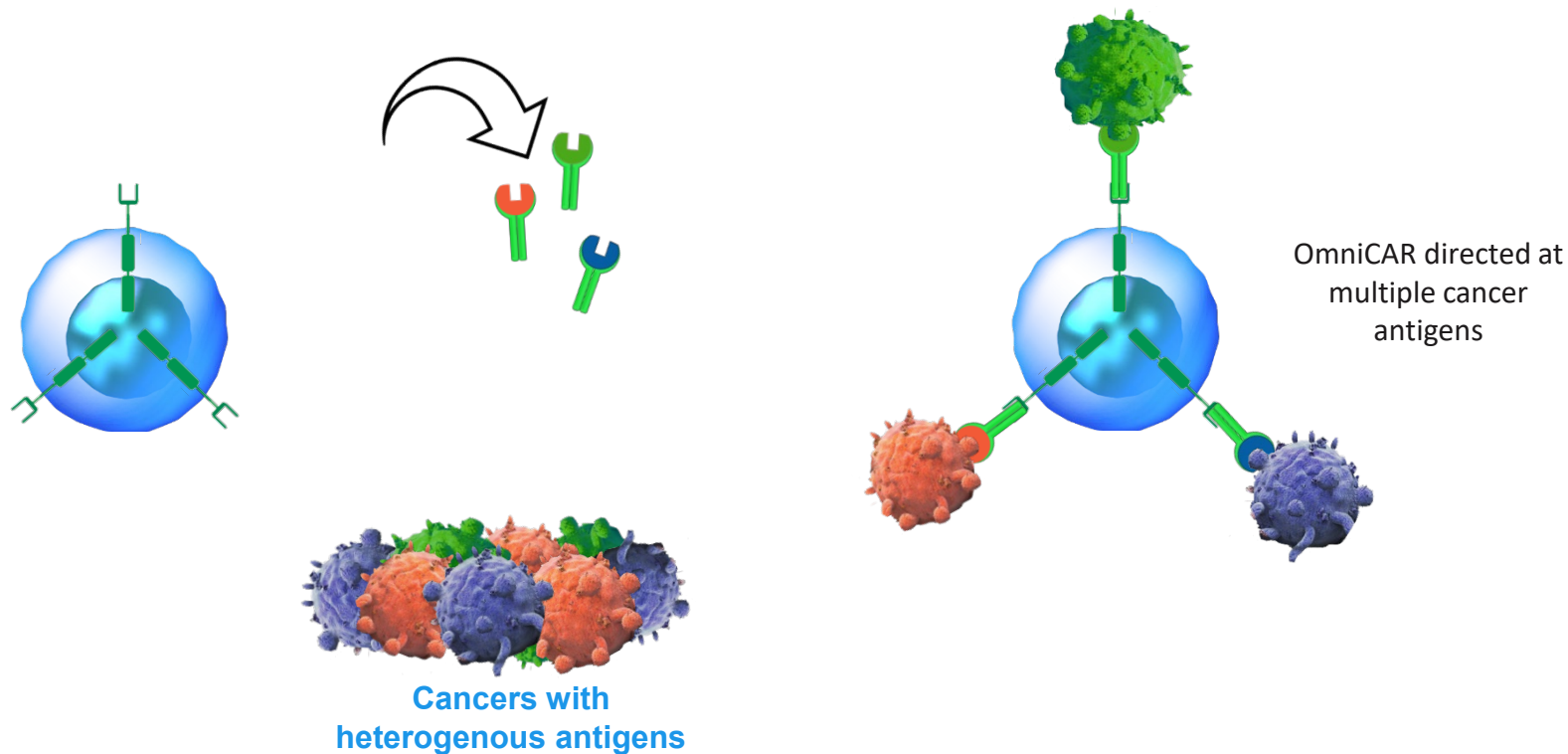
# Safety: Built-in on/off switch



# Ability to Target Multiple Antigens *Sequentially*



# Ability to Target Multiple Antigens *Simultaneously*





# With OmniCAR, this is just the start for CAR-T



- Seeking to enhance **current generation CAR-Ts**....
- ...& more significantly, **help realise the broader potential of CAR-T**, which is much bigger opportunity!

## Current generation CAR-T

- Autologous T cells
- B-cell malignancies

## Cell types

- Allogeneic (off the shelf) T-cells
- iPSC derived cells
- NK cells

## A whole new toolbox of Binders

- Re-purposing antibodies into next-gen CARs will **accelerate the whole field**
- Non-CAR-T companies can leapfrog into next-gen CAR-T

## Overcoming T-cell Exhaustion

## Companion diagnostics

## Adaptable and tailored CARs

## Addressing escape & relapse

## Other hematological malignancies

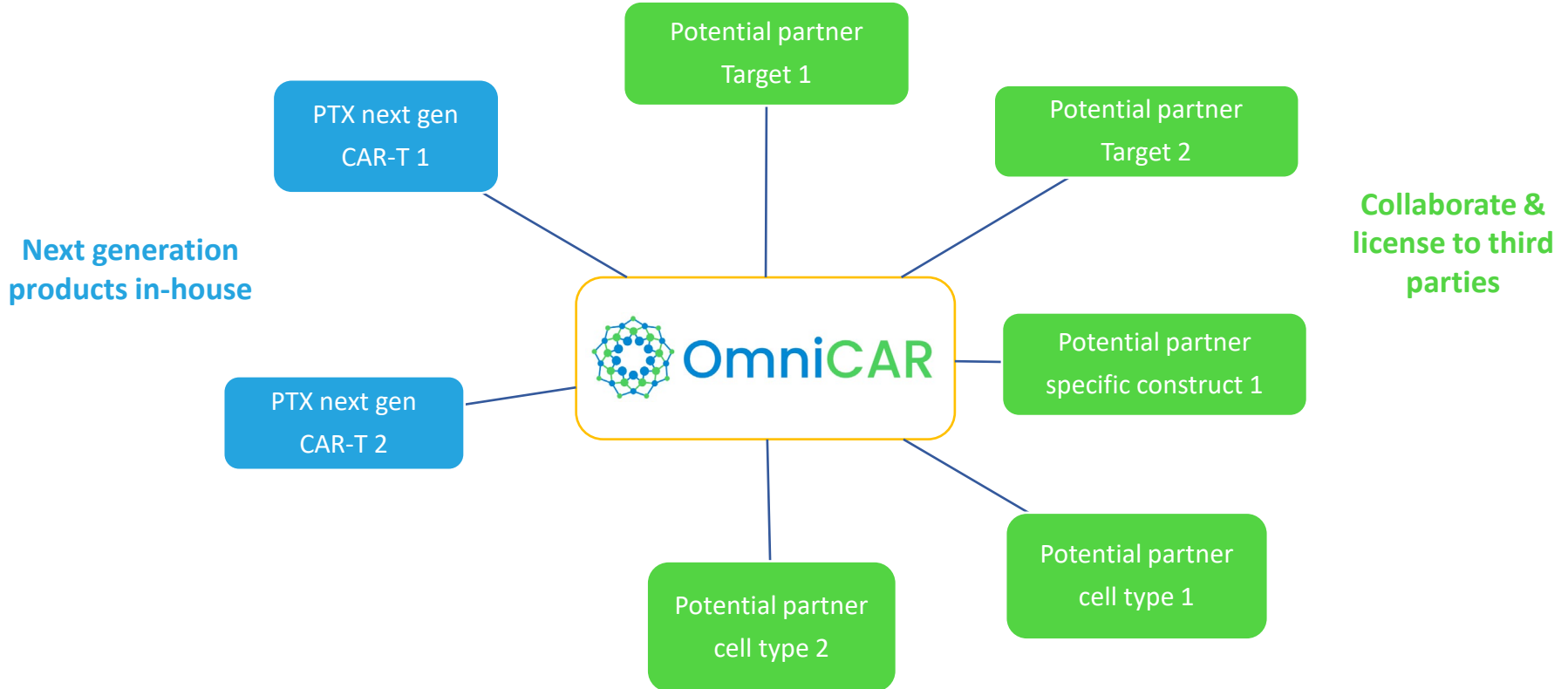
## Solid tumours!!!

- Novel antigens & optimising antigen combinations
- Overcoming trafficking
- Tumor microenvironment

## Safer CAR-T = more applications

- Safer and more controllable next-gen therapies will bring CAR-T to many more patients
- Opens opportunities beyond oncology

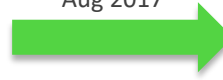
# OmniCAR Platform Business Model



# CAR-T deal activity



Bought for  
**US\$11.9B**  
Aug 2017



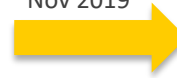
First generation  
CAR-T...



Bought for  
**US\$9B**  
Jan 2018



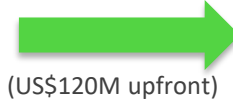
Bought for  
**US\$74B**  
Nov 2019



...now  
next generation CAR-T

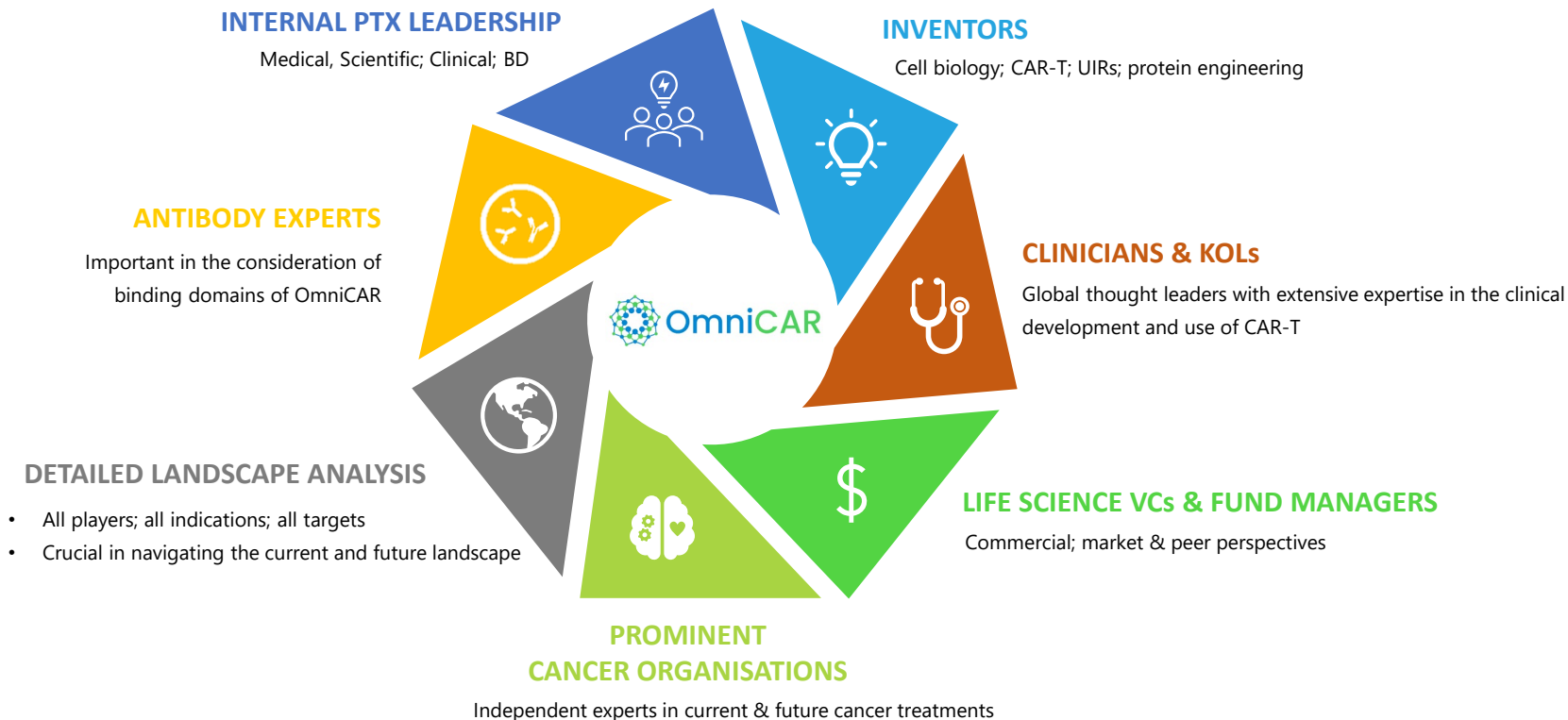


Bought for  
**US\$665M**  
Dec 2019



**XYPHOS**  
(Pre-clinical peer)

# Thorough strategic review for internal OmniCAR programs



## TARGETED THERAPIES

- PTX-100: Ph1b basket study underway
- PTX-200:
  - AML: Ph1b underway
  - Evaluating new orphan indication trial – extremely encouraging biomarker-driven study in an area of strong unmet need
  - Breast Cancer: evaluating biomarker driven study & hormone therapy combination in ER+ disease
  - Ovarian cancer: evaluating new combination

## CELL THERAPY ENHANCEMENTS

- 2 projects underway at Peter Mac & Uni Adelaide/Carina

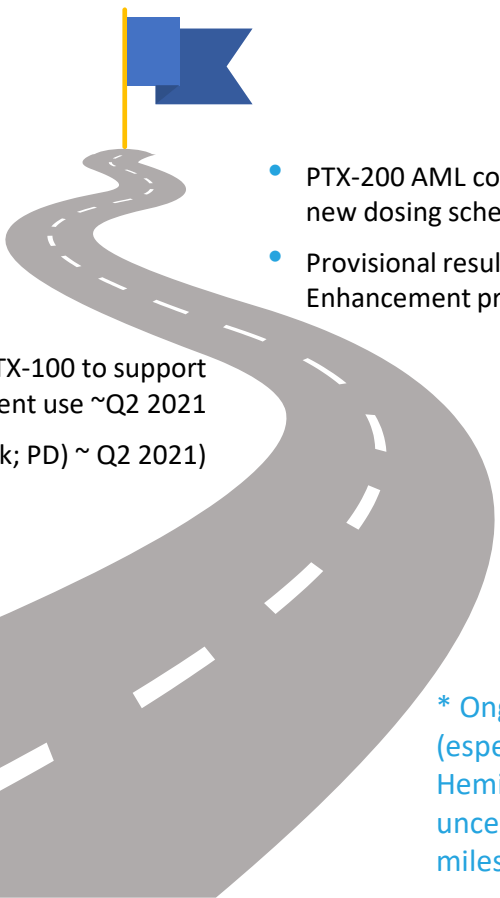
## OmniCAR

- Currently undertaking strategic review of opportunities for in-house programs
  - 1-2 lead programs
  - Follow-on programs exploiting different OmniCAR capabilities
- Commence BD activity for collaboration & licensing

## DEEPENING CAR-T EXPERTISE

- Spearheaded by Allen Ebens (early hire at Juno to establish their scientific operations)
- Prof Phil Darcy joined SAB
- Dr Dan Shelly with cell therapy expertise appointed VP – Business Development & Alliances
- About to appoint CAR-T expert as pre-clinical project manager
- Multi-disciplinary CAR-T SAB being assembled

# In the next 12 months we will work towards:

- 
- Ongoing business development activities
    - Continuing to build awareness among investors, clinicians and corporates
  - Completing manufacturing of additional PTX-100 to support increased patient use ~Q2 2021
  - PTX-100 basket study top line results (safety; Pk; PD) ~ Q2 2021
  - Completing recruitment of the PTX-100 PK/PD study (end 2020/Q1 2021)
    - Initiation of OmniCAR programs ~Q1 2021
  - Covid-19 Doherty results (imminent)
  - Announcement of OmniCAR programs (Dec 20)
  - PTX-200 AML completion of Ph1b new dosing schedule
  - Provisional results of Cell Therapy Enhancement programs

\* Ongoing impacts of COVID-19 (especially in Northern Hemisphere) creates uncertainty around timing of milestones

# Compelling investment case!



**Well funded** to deliver value-adding milestones



Best in class, unique platform. Enviably **positioned ahead of a huge wave in CAR-T**



**Many shots on goal** for substantial value creation



Creating **next generation CAR-T** products for Prescient



Two differentiated targeted therapies in clinical trials, each a **potential company-maker**



**Earlier monetisation opportunities** as an enabling technology for 3<sup>rd</sup> parties



**Thank you!**

ASX code: PTX

[www.ptxtherapeutics.com](http://www.ptxtherapeutics.com)