



Anti-GPC-1 Antibody for Targeted Radiotherapy of Cancers

Pitch Deck

Dr Brad Walsh, CEO

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**Investments leveraged by 43% cash rebate on
R&D spend from Australian Government
Unique target for multiple solid tumors
First-in-Class clinical stage product
Excellent safety profile
Clear development pathway
IP fully owned by company with long patent lives**

Image the cancer. **Treat the cancer.**

Why GlyTherix?

Targeted radiotherapy company with clinical stage product showing excellent safety profile in **high unmet need cancers**



First-in-class molecule

Targeting Glypican-1 (GPC-1) expressing tumors with **high specificity and no off-target binding**



Large addressable US market

US\$ 21.7 Billion – based on three lead cancer indications



IP and publications

Extensive IP portfolio owned outright by GlyTherix
Extensive **peer reviewed publications**

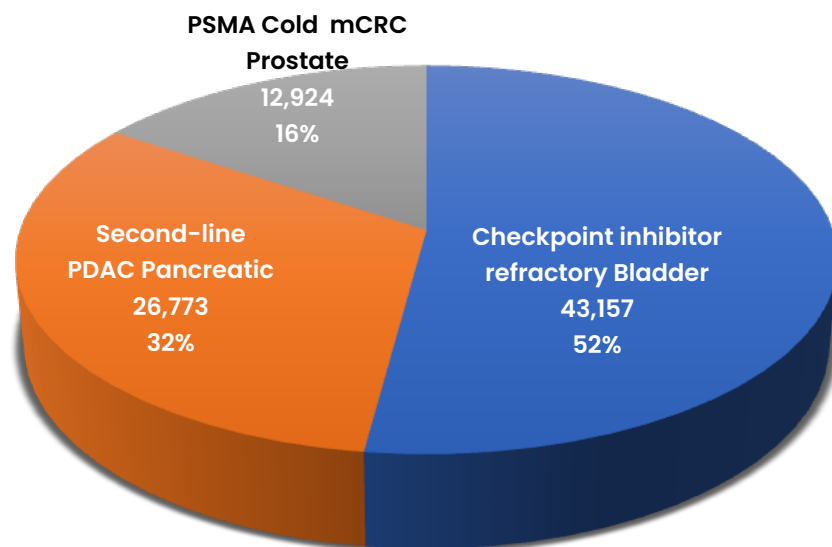


Clear development pathway

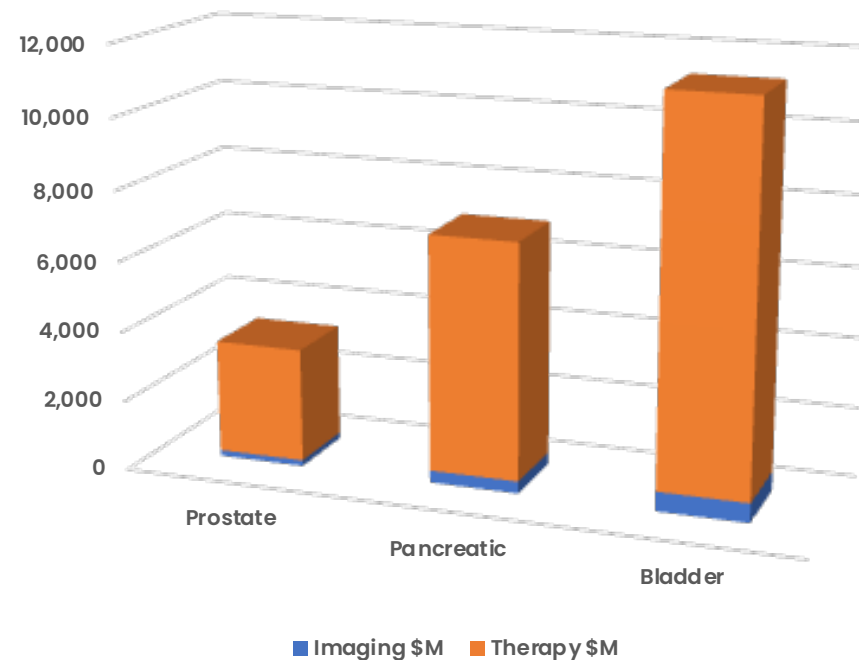
Completed Phase 1a human clinical trial with **strong safety profile**
Robust manufacturing consortium

Unmet Need and Total Addressable Market

Number of Annual Metastatic Cases in US and EU



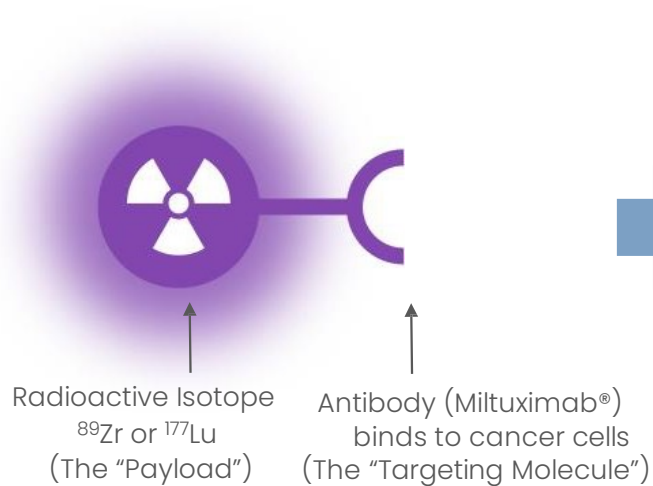
TAM by Indication



Large Total Addressable Market \$21.7B

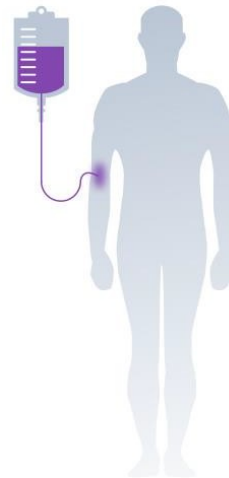
Miltuximab® Precisely Delivers Targeted Radiation to Cancer Cells

1. Theranostic Drug



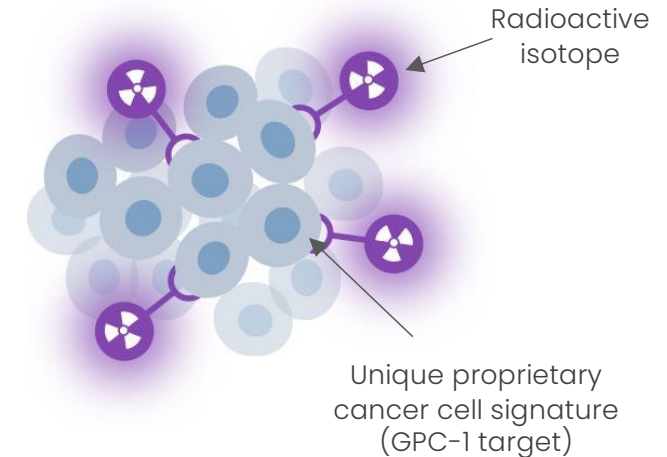
GPC-1 target on the cancer cell is the 'address' that the radiation is delivered to

2. Intravenous injection



Drug administered via blood stream and binds to cancer cells, wherever they are, including small metastases

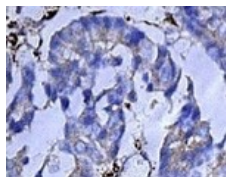
3. Targeted delivery of radiation



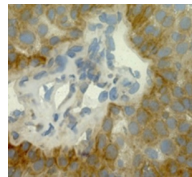
- Low energy isotopes used to image patient's cancer
- High energy isotopes destroy cancer cells

Novel Target: Glypican-1 (GPC-1)

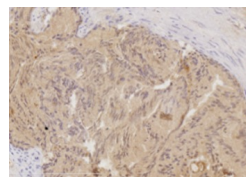
- **Multiple cancers enhancing value proposition** – lung, pancreas, bladder, prostate, glioblastoma, esophageal, breast, ovarian, cervical, mesothelioma and colorectal cancers (IHC of selected tissue below)
- **Excellent safety profile** – GPC-1 not detected in normal tissues
- **Target for aggressive cancer types** – critical role in growth/invasion/metastasis, associated with poor clinical outcomes
- **No other clinical programs** in the world targeting GPC-1 – **no direct competitors**
- **First in class** antibody, Miltuximab®, has shown excellent clinical safety and preclinical safety and efficacy
- **Robust patent estate** – 5 families registered worldwide in 21 countries



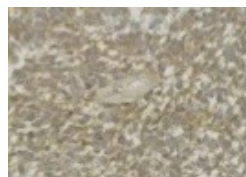
IHC: Pancreas



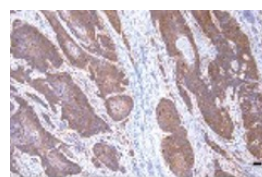
Bladder



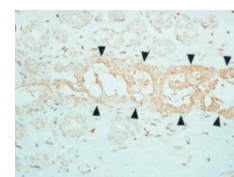
Prostate



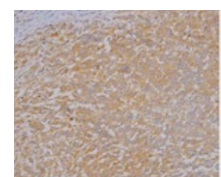
Glioblastoma



Esophageal



Breast



Cervical

Choosing Lead Clinical Indications

Characteristic	Prostate	Pancreas	Bladder
High % cancers with GPC-1 overexpression	78%	79%	75%

Extensive preclinical safety and efficacy data

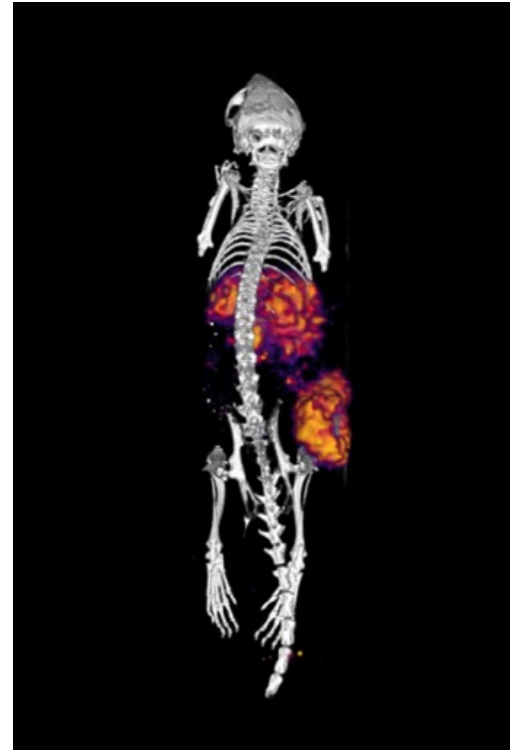
Dosimetry data for lutetium derived from Phase 1a trial
Prior clinical safety data from FIH study

High expression GPC-1 patients have poor prognosis

Additionally	
Prostate	<ul style="list-style-type: none"> ✓ 20-30% of CaP patients are low PSMA – unmet need for new therapies ✓ GPC-1 upregulated in treatment emergent Neuroendocrine Prostate Cancer
Pancreas	<ul style="list-style-type: none"> ✓ GPC-1 expressed in fibrotic pancreatic stromal cells as well as pancreatic cancer cells – opportunity to target both
Bladder	<ul style="list-style-type: none"> ✓ Miltuximab® antibody originally raised against bladder cancer cells

Diagnostic Imaging Product: ^{89}Zr -Miltuximab[®]

- Clear manufacturing pathway
- Shown to target prostate and glioblastoma tumor xenografts *in vivo*
- Phase Ib - image patients to show where tumors are located and who is suitable for therapeutic dose with ^{177}Lu -Miltuximab[®]



A. Drug targets human prostate tumor xenograft in mouse

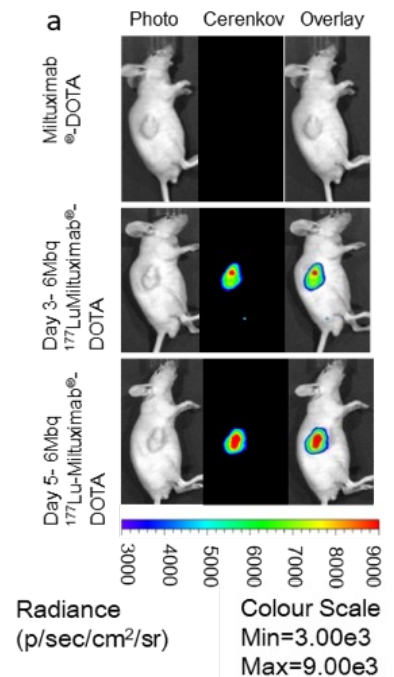
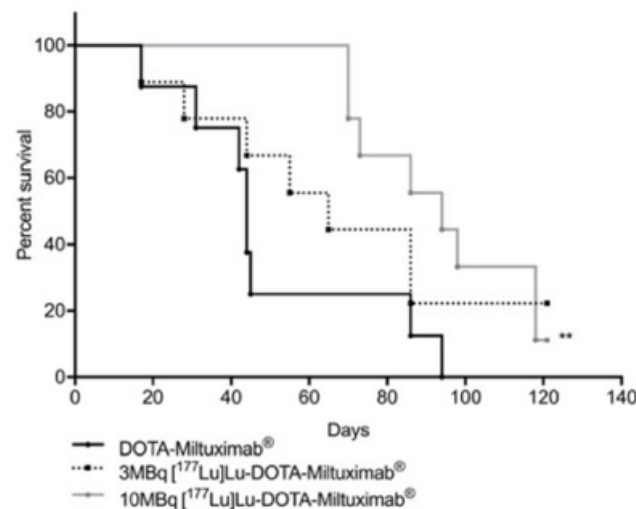
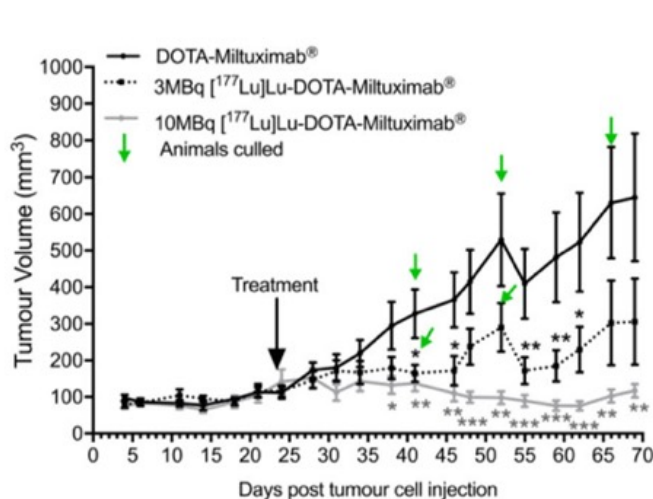


B. Drug targets human glioblastoma tumor xenograft in mice

Therapeutic Drug Product: ^{177}Lu -Miltuximab[®]

Demonstrated dose dependent inhibition of tumour growth and enhanced survival

Imaging of mice with tumor (grown in flank) showing excellent targeting

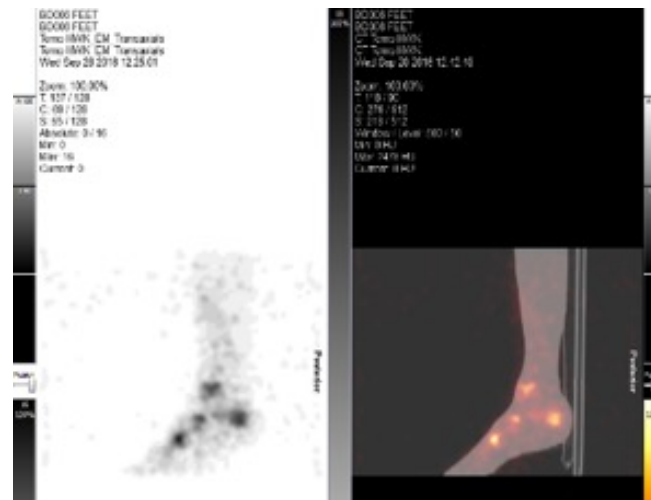


- Single dose of ^{177}Lu -Miltuximab[®] treatment in prostate tumor model
- Actual prostate tumor inserted and grown in mice for *in vivo* testing of drug

Phase 1a Clinical Trial – First-in-World Imaging Study Demonstrated Safety and Tumor Targeting

Key Outcomes

- Primary endpoints of safety and tolerability met in all 12 patients
- Up to 25 mg dose showed no drug related adverse reactions
- Secondary endpoints showed:
 - Targeting present in more advanced metastases
 - Dosimetry showed best imaging timepoint 24 to 48 hr post-infusion



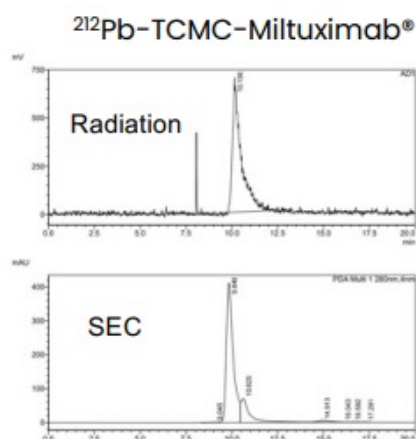
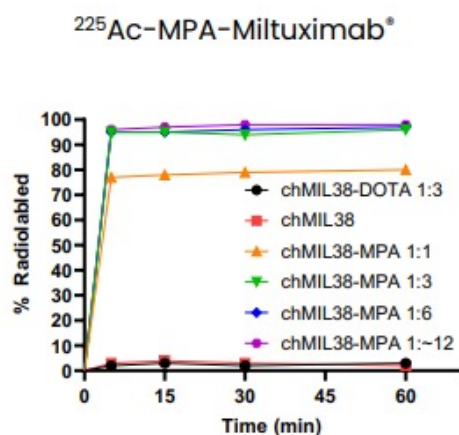
Images show clear targeting of antibody to prostate metastases

P2: Foot Uptake in bone metastases at 24h

Alpha Therapy Pipeline

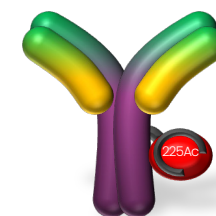
GlyTherix is a partner in the Advanced Manufacturing of Targeted Alpha Radiopharmaceuticals R&D Hub

- AMTAR has a focus on alpha emitters ^{225}Ac Actinium and ^{212}Pb Lead
- Alpha Particles have a higher energy emission and thus are more effective in killing cancer cells
- Promising preclinical data with Miltuximab® for both radioisotopes



Treat the cancer

Patients showing targeting selected for ^{225}Ac -Miltuximab® therapy

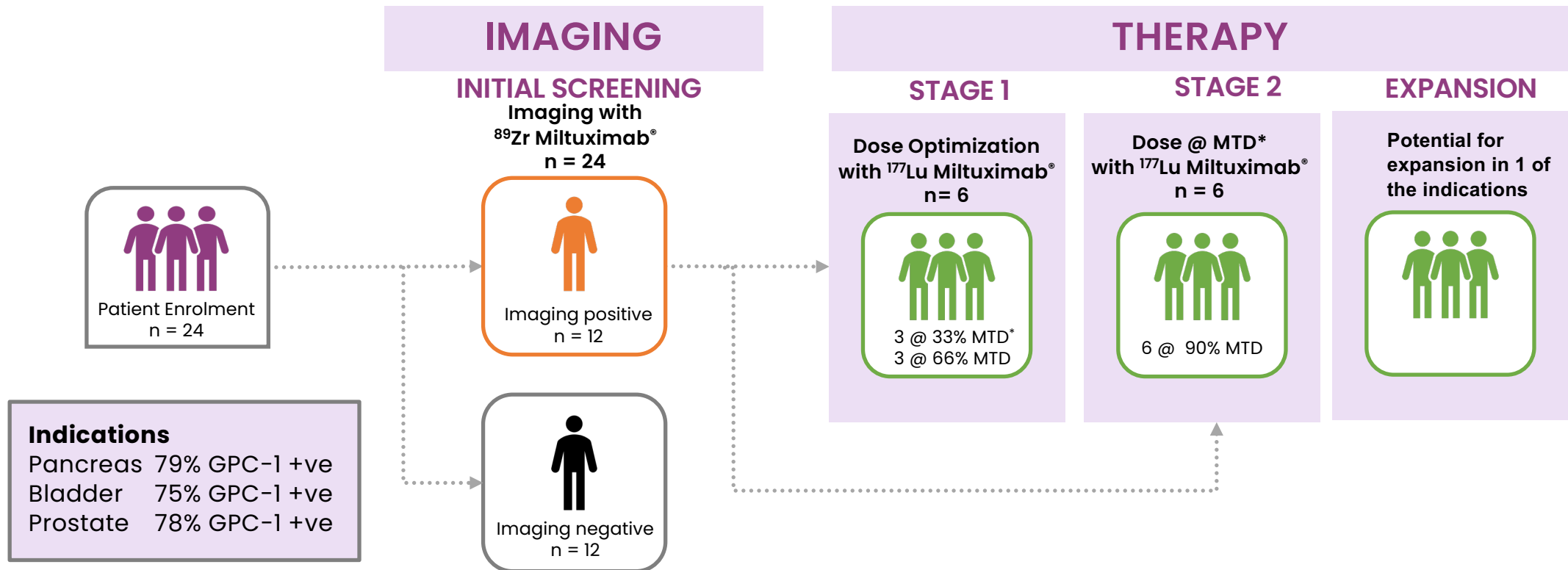


Therapeutic radiation delivered to the tumor

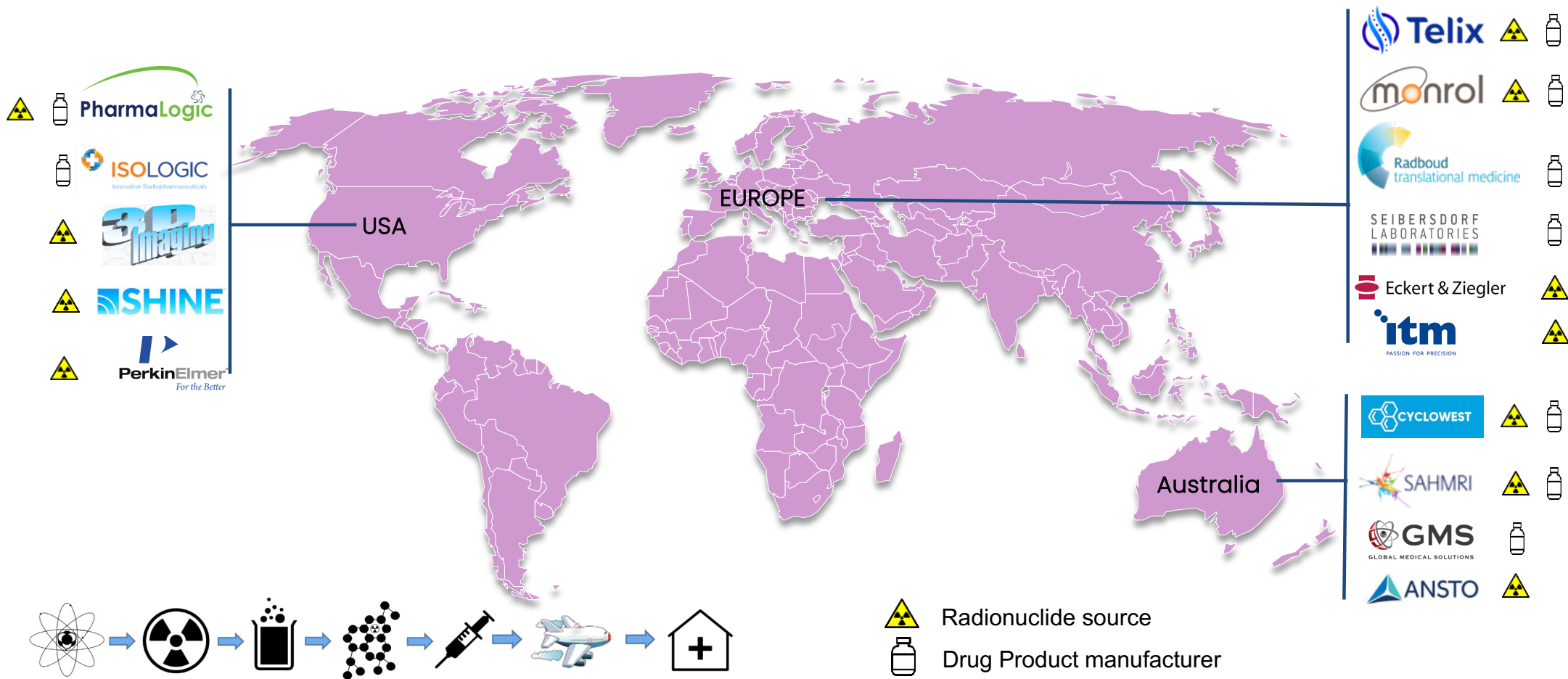
Phase 1b – Time from First to Last Patient – 10 Months

Trial planned for late-stage cancer patients with no other treatment options

- ✓ Patients first imaged to show GPC-1 in tumors (have assumed 50% have GPC-1)
- ✓ Patients showing GPC-1 then progress to escalating therapeutic doses to assess efficacy



GMP Radiopharmaceutical Production Network Established



Experienced Executive Management and Advisory



Dr Brad Walsh
CEO and MD



David Burdis
Chief Financial Officer/
Company Secretary



Dr Douglas Campbell
Head of Research
and Development



Dr Yanling Lu
Head of Chemistry,
Manufacturing and
Controls



Dr Gabriel Liberatore
Strategic Advisor

Professor David Gillatt (Chair)
Professor of Urological Oncology
Macquarie University Hospital

Dr Neal Shore
CMO Surgery/Urology
GenesisCare

Dr John Babich
President and CSO of
Ratio Therapeutics



Professor Howard Gurney
Director of Clinical Trials
Macquarie University
Hospital



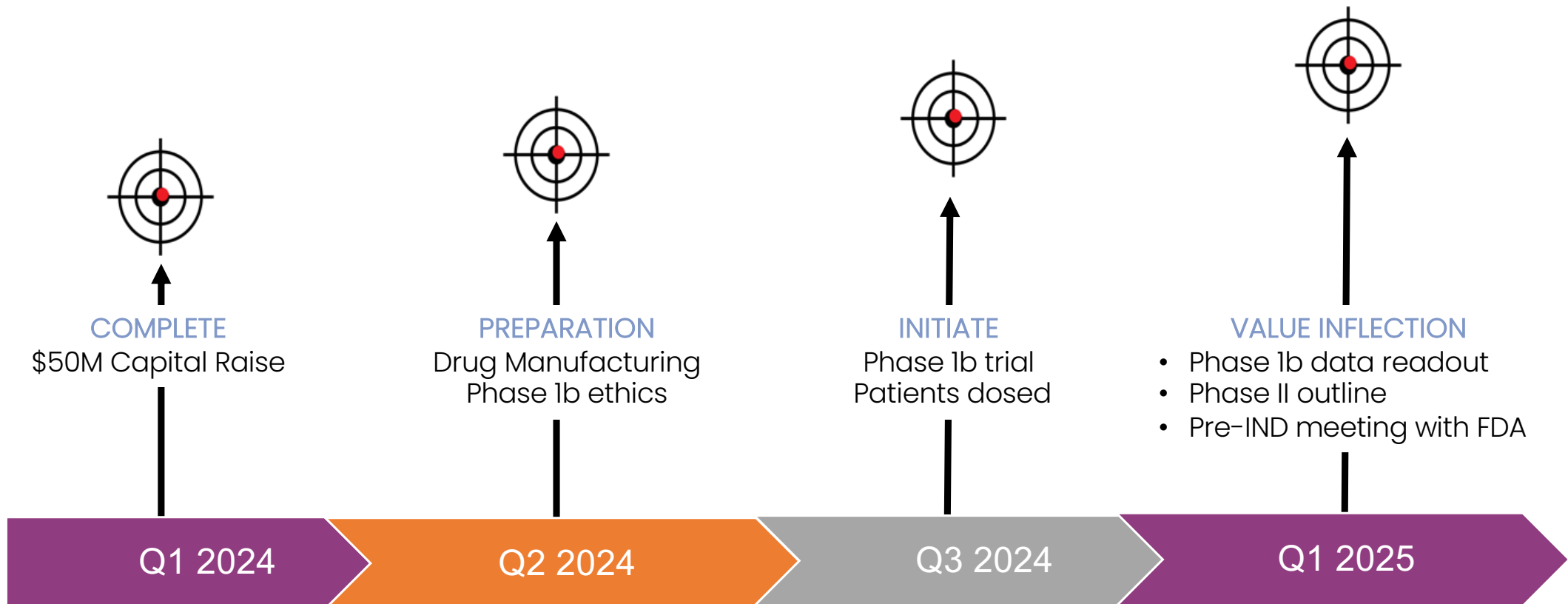
Dr Alan Harris
NYU School Medicine
Led clinical development
and approval of octreotide
(Lutathera)



Dr Elcin Zan
Weill Cornell Medicine
dual board-certified
radiologist specializing in
Neuroradiology and
Nuclear Medicine



Major Inflection Points in the next 18 months








Use of Proceeds to Achieve Major Value Inflection

Clinical and Pre-Clinical Programs	Comment	Outcome
Antibody manufacturing and bioconjugation	Underway	GMP antibody clinical products
Radiolabelling process development	Underway	Targeted radiotherapy product ready for Phase Ib
Australian Phase Ib clinical trial	Phase Ib trial	Targeted radiotherapy data, selection of Phase 2 indication/s, IPO ready
Pipeline and other preclinical development	Planned	Other studies including investigator-initiated trial
Regulatory and other consultants	Ongoing	Advice re trials and commercialisation strategy
Staff, space, KOLs, administration	Overheads etc	2yr funds for staff and overheads
Subtotal		
Less Non-Dilutive Funding		
Government Grants		
R&D Tax Rebate @ 43.5% of R&D Spend		Cash government incentive
Balance –funded by capital raise		

Investors in Similar Companies Have Seen Significant Value Generation & Impressive Return On Investment

Company and price

					
US\$2.9B	US\$3.9B	US\$2.1B	US\$641M	US\$1.4B	US\$4.1B

Acquirer and date






					
Dec 2013	Oct 2017	Oct 2018	Oct 2019	Oct 2023	Dec 2023



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www.glytherix.com