



# Investor Presentation

23 July 2024

ASX: TLX



Illustration showing TLX250 binding to carbonic anhydrase IX and internalisation

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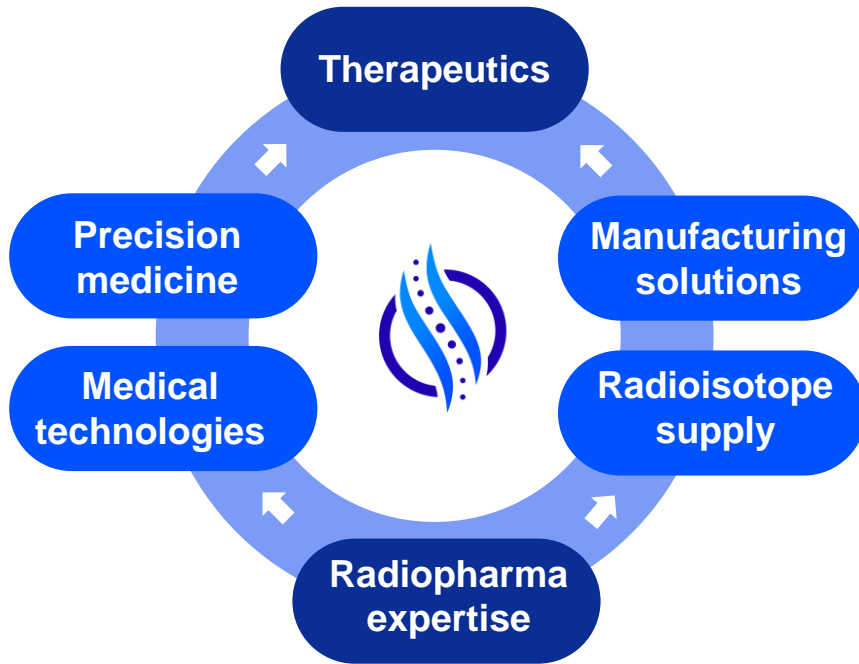
All figures are in AU\$ unless stated otherwise.



# A global leader in theranostics and precision medicine

Telix is uniquely positioned in the fast-growing radiopharmaceutical industry

## Integrated theranostic ecosystem



### Industry-leading therapeutic pipeline

Highly differentiated, late-stage assets in prostate, kidney and brain cancer, with **multiple clinical milestones ahead**



### Underpinned by a commercial portfolio generating revenue ~\$US239M<sup>1</sup> in H1 2024

**Opportunity to build on Illuccix®** 3 x regulatory filings progressing for Zircaix®<sup>2</sup>, new PSMA<sup>3</sup> imaging product and Pixclara™<sup>4</sup>



### World-class supply chain and manufacturing

Expanding in-house manufacturing capacity and capability, a **key source of competitive advantage**



1. Telix ASX disclosure 18 July 2024.
2. Zircaix®: TLX250-CDx for kidney cancer imaging, brand name subject to final regulatory approval.
3. Prostate-specific membrane antigen.
4. Pixclara™: TLX101-CDx for glioma imaging, brand name subject to final regulatory approval.

# Theranostics: A new, fundamental pillar of oncology

## Changing the way we find and treat cancer and disease

Radiopharmaceuticals deliver targeted radiation directly to tumours, limiting damage to surrounding healthy tissue

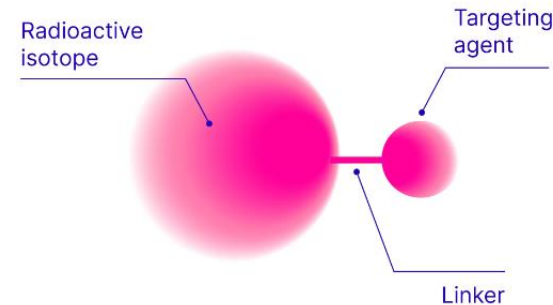
**Highly selective:** Targeting agents – with high affinity for cell-surface biomarkers – carry radiation to the tumour site

**Theranostic approach:** The radioactive payload (isotope) can be used to produce an image (*see it*) or deliver therapy (*treat it*)

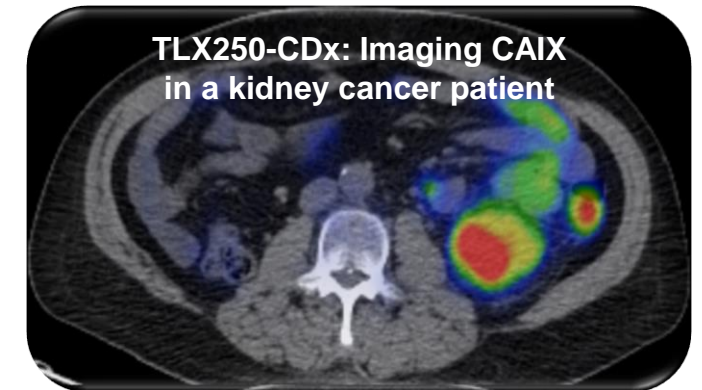
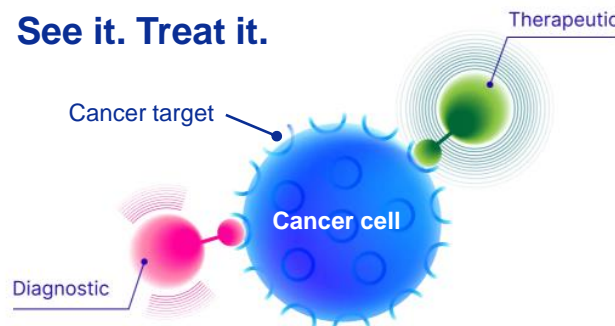
**Experts in radiation biology:** Targeting agent and isotope is selected for each indication

**Protected:** Telix's intellectual property portfolio comprises 128 owned patents and 234 in-licensed patents<sup>1</sup>

### Targeted radiation drug











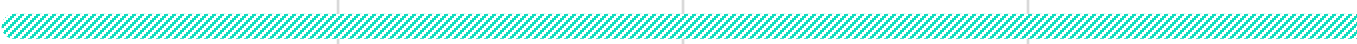


### See it. Treat it.



Images from STARLITE-2 study.  
Credit: Memorial Sloan Kettering Cancer Center.

# Core pipeline: Key disease areas (alpha and beta emitters)

	TARGETING AGENT	ISOTOPE	Dx/ Tx <sup>8</sup>	PHASE 1	PHASE 2	PHASE 3	COMMERCIAL
<b>Prostate PSMA<sup>1</sup></b>	Antibody	<sup>177</sup> Lu	Tx				
	Antibody	α (alpha)	Tx				
	Small molecule	<sup>68</sup> Ga	Dx				
<b>Kidney CAIX<sup>2</sup></b>	Antibody	<sup>177</sup> Lu	Tx				
	Antibody	<sup>89</sup> Zr	Dx				
<b>Brain LAT1 &amp; LAT2<sup>3</sup></b>	Small molecule	<sup>131</sup> I	Tx				
	Small molecule	<sup>18</sup> F	Dx				
<b>STS<sup>4</sup> PDGFRα<sup>5</sup></b>	Antibody	Undisclosed	Tx				
	Antibody	<sup>89</sup> Zr	Dx				
<b>BMC<sup>6</sup> CD66<sup>7</sup></b>	Antibody	<sup>90</sup> Y	Tx				
	Antibody	<sup>99m</sup> Tc	Dx				

1. Prostate-specific membrane antigen.  
2. Carbonic anhydrase IX.  
3. L-type amino acid transporters 1 & 2.

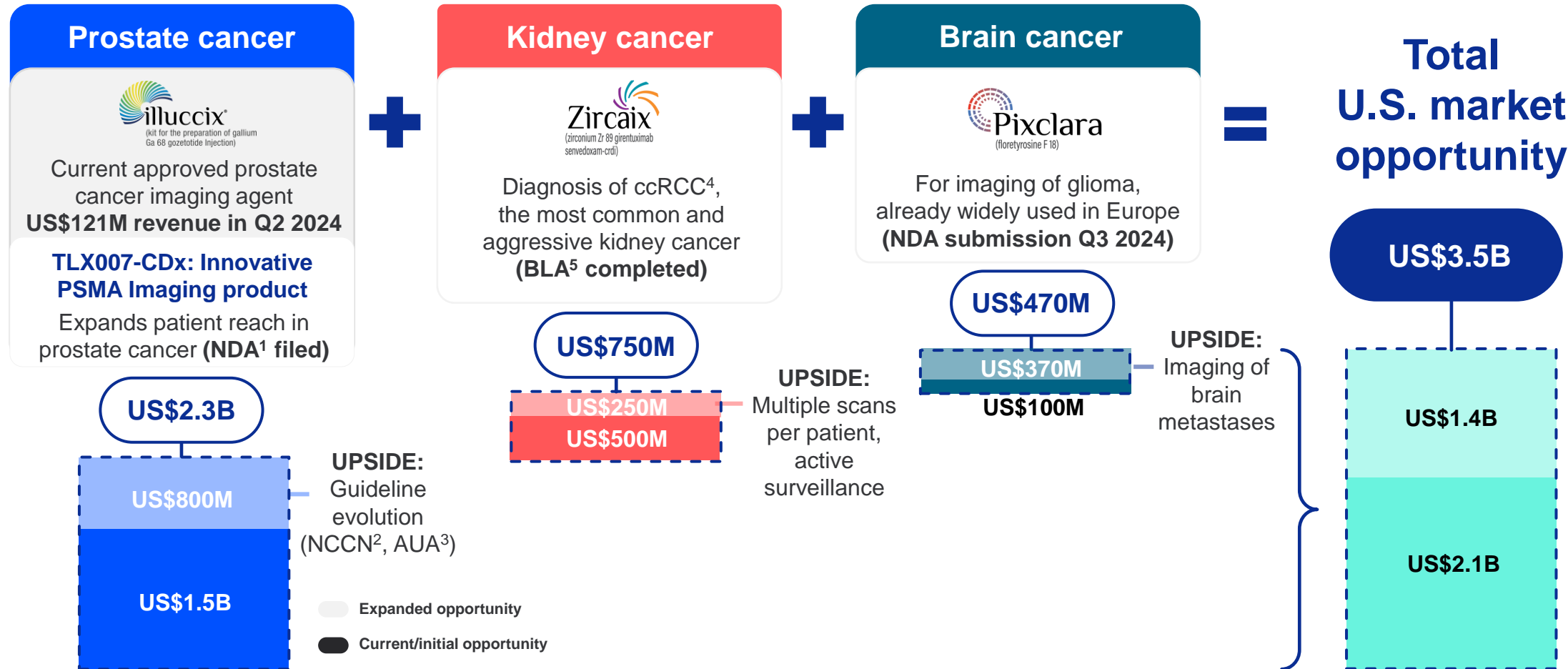
4. Soft tissue sarcoma.  
5. Platelet derived growth factor receptor alpha.  
6. Bone marrow conditioning.

7. Cluster of differentiation 66.  
8. Dx = diagnostic / Tx = therapeutic.  
9. Brand name subject to final regulatory approval.

10. Marketed under license by Curium Pharma.

# Precision diagnostics presents a near-term growth opportunity

Telix's imaging portfolio has a U.S. market opportunity of US\$3.5B with potential to grow



1. New drug application.

2. National Comprehensive Cancer Network®.

3. American Urological Association.

4. Clear cell renal cell carcinoma.

5. Biologics license application.

Zircaix and Pixclara brand names subject to final regulatory approval.

# Therapeutics will be the growth engine of radiopharma

Global market forecast to grow by 18% per annum to reach US\$35B in 2031<sup>1</sup>

Therapeutics is the fastest growing segment of the global radiopharmaceutical market:

- In 2020, radiotherapeutics represented 21% of the radiopharmaceutical market, by 2031 it is expected to represent 75% of a US\$35B market
- Telix has multiple opportunities with late-stage assets in prostate, kidney and brain cancer, and an expanding early-stage portfolio

## U.S. market for lead therapeutic indications

US\$8.7B<sup>2</sup>



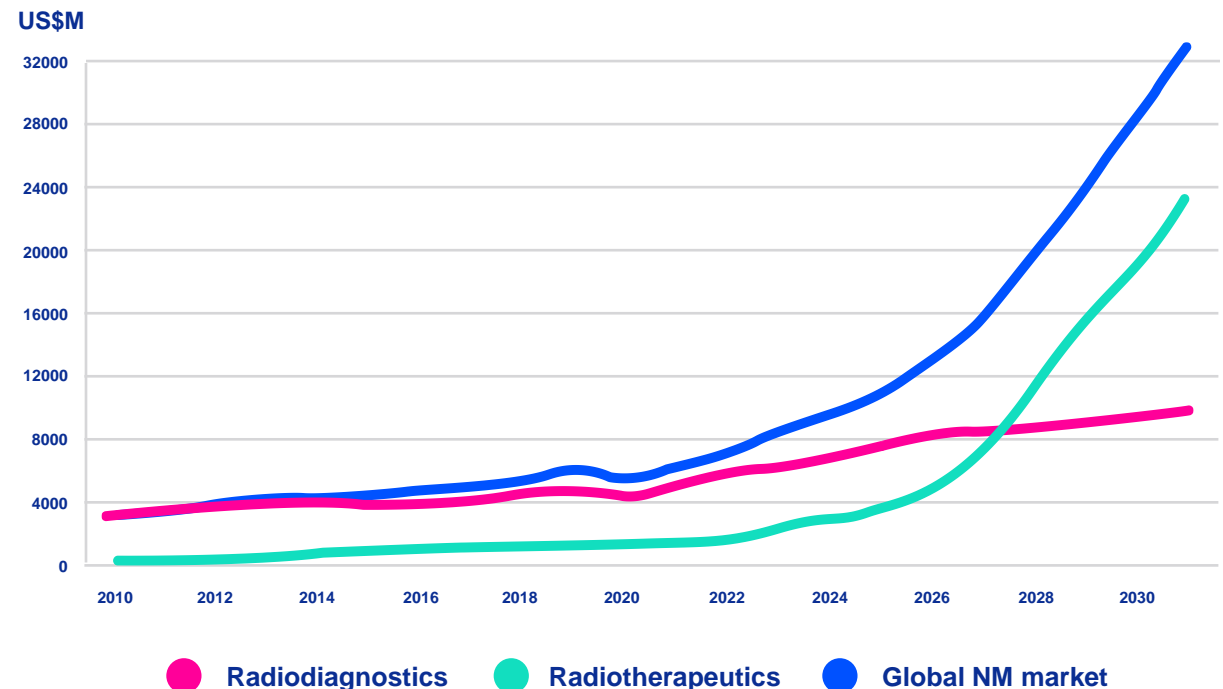
US\$6.0B<sup>3</sup>



US\$2.1B<sup>4</sup>



## Radiodiagnostics and radiotherapeutics growth 2010-31



1. Source: MEDraysintell

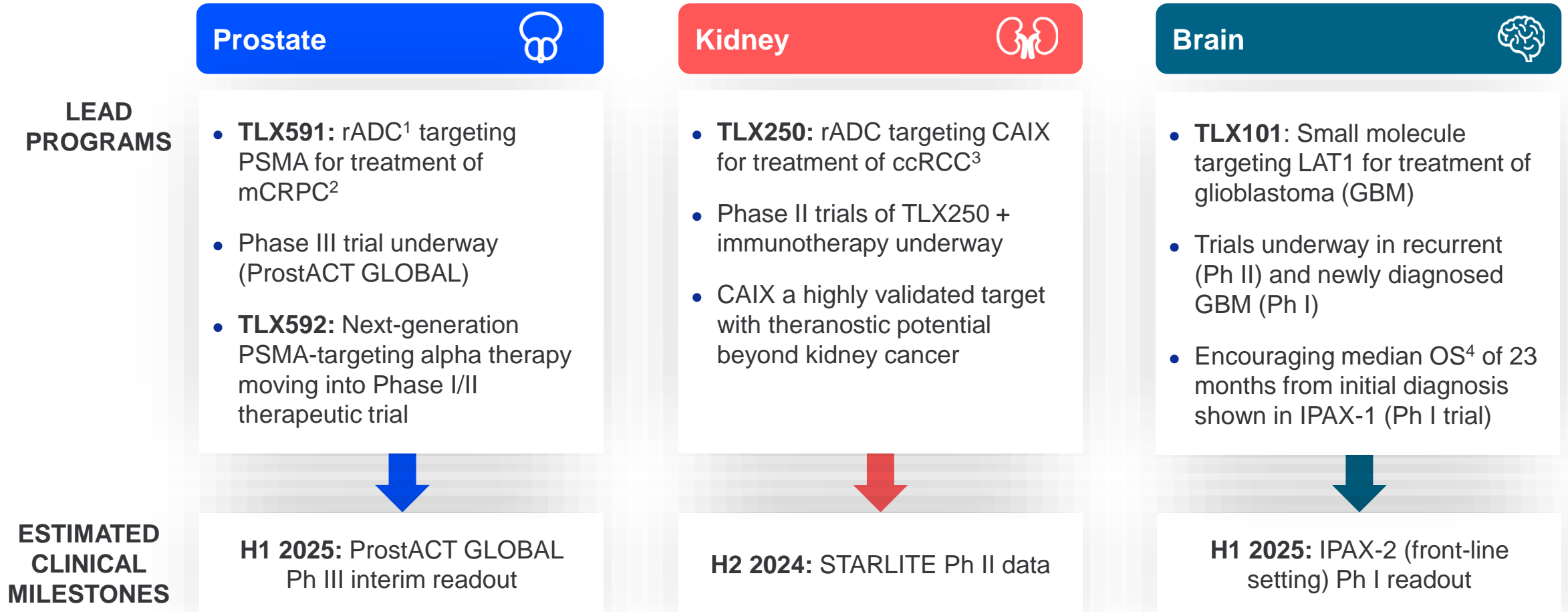
2. Datamonitor prostate cancer patient based forecast model.

3. Datamonitor RCC patient-based forecast model.

4. Management estimates.

# Late-stage therapeutic programs

Highly differentiated assets, with clinical inflection points approaching



1. Radio antibody-drug conjugate.  
2. Metastatic castrate-resistant prostate cancer.

3. Clear cell renal cell carcinoma.  
4. Overall survival.

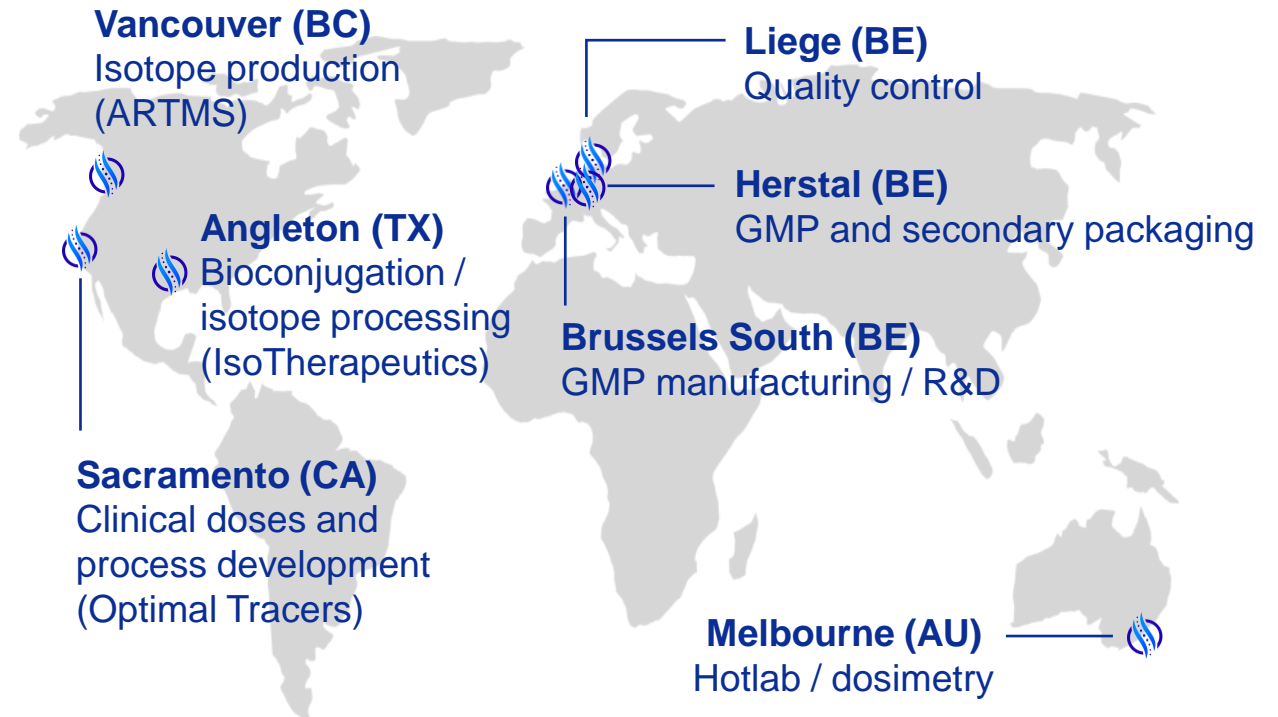


# Supply chain and manufacturing is integral in radiopharma

Telex is equipped to deliver patient doses globally

**Expanding in-house development and production capacity, underpinned by a robust global supply chain**

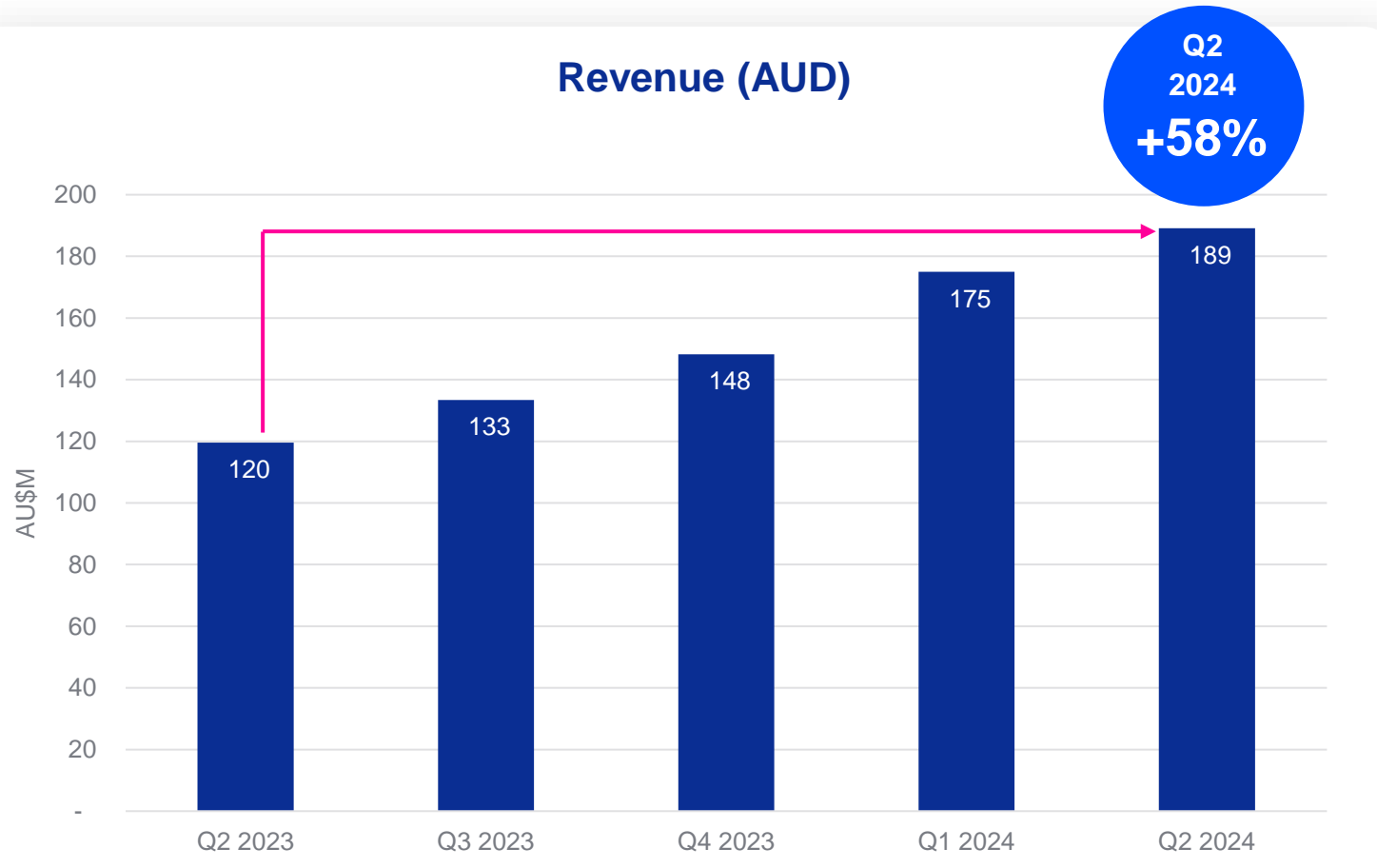
- End-to-end process development and manufacturing
- In-house radiochemistry and clinical dose production
- Isotope production and processing
- Belgian facility one of the largest GMP<sup>1</sup> radiopharmaceutical production facilities in Europe
- “AlphaLab” for specialty R&D



**Vertical integration: Global production, process development and R&D sites**

# Strong product take up has driven attractive revenue growth

Established track record of strong financial stewardship



### Key financial metrics (Q1 2024)

Gross margin

**66%**

62% Q1 2023

Operating profit

**\$29M**

**US\$19M**

\$5.6M (US\$3.7M) loss  
Q1 2023

R&D costs

**\$38M**

**US\$25M**

Cash balance

**\$123M**

**US\$80M**

March 31, 2024

# Our strategy: Four key areas of investment

Multiple near-term catalysts ahead



2024	H1 2025
<ul style="list-style-type: none"><li>✓ ProstACT SELECT (TLX591) rPFS<sup>1</sup> data</li></ul>	<ul style="list-style-type: none"><li>IPAX-2 and IPAX-Linz (TLX101) therapy studies readouts</li></ul>
<ul style="list-style-type: none"><li>STARLITE (TLX250 + immunotherapy) Phase II readout</li></ul>	<ul style="list-style-type: none"><li>ProstACT GLOBAL (TLX591) Ph III interim readout</li></ul>
<ul style="list-style-type: none"><li>ProstACT GLOBAL recruitment at U.S. sites</li></ul>	<ul style="list-style-type: none"><li>TLX592 “alpha” therapeutic trial update</li></ul>
<ul style="list-style-type: none"><li>✓ ARTMS and IsoTherapeutics acquisitions</li></ul>	
<ul style="list-style-type: none"><li>✓ Zircaix®<sup>2</sup> (TLX250-CDx) BLA completion</li></ul>	
<ul style="list-style-type: none"><li>ZIRCON first peer-review publication</li></ul>	
<ul style="list-style-type: none"><li>Pixclara™<sup>2</sup> (TLX101-CDx) NDA submission</li></ul>	
<ul style="list-style-type: none"><li>Illuccix® Brazil, EU and UK approval decisions</li></ul>	
<ul style="list-style-type: none"><li>TLX300 clinical program commences in soft tissue sarcoma</li></ul>	



1. Radiographic progression-free survival.  
2. Brand name subject to regulatory approval.

# Our M&A strategy is closely aligned with our strategic priorities

Inorganic growth provides opportunities to rapidly differentiate and add value

Adding sought-after resources,  
capabilities and value-creating assets

Focus  
areas



Supply chain and  
manufacturing



Clinical-stage pipeline  
expansion



Indication and  
franchise expansion

Strategic  
rationale

Buy v Build: adding core  
capabilities and supply  
chain security and  
control



Accretive assets in our  
key disease focus areas,  
with a clear pathway to  
revenue generation



Expand commercial  
opportunities via  
complementary  
technologies and skills



DEDIC AID



# Precision medicine (diagnostics) portfolio



(kit for the preparation of gallium  
Ga 68 gozetotide Injection)



**Pixclara**  
(floretyrosine F 18)

**Zircaix**  
(zirconium Zr 89 girentuximab  
servedoxam-crdi)

**TLX007-CDx PSMA  
imaging product**



# The Iluuccix® difference

The leading gallium-based PSMA-PET<sup>1</sup> imaging agent in the U.S.

## CLINICAL ACCURACY

Pinpoint micrometastases at the earliest signs across stages of prostate cancer in a broad range of patients<sup>2</sup>

## HIGH-QUALITY IMAGES


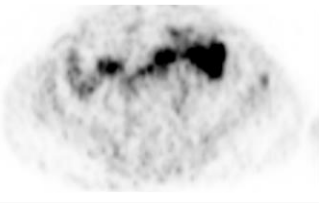

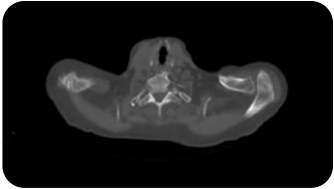
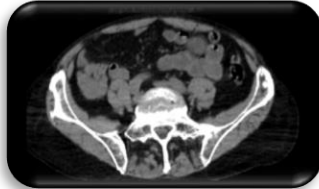
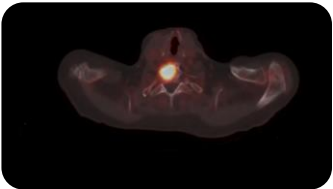
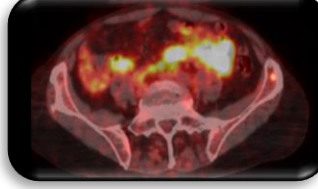
High-quality images across vital regions, with scan time  $\leq 30$  minutes and trained specialists ready to help

## RELIABLE DISTRIBUTION

Order directly from over 200 radiopharmacies in the U.S. with flexible scheduling and on-time delivery that arrives when you need it

## END-TO-END SUPPORT

Dedicated industry-leading support at every step, including onsite onboarding, educational resources, and ongoing training

	C7 Vertebral body metastasis	Left Iliac metastasis	Fused MIP
PET positive patient			
CT			
Fused PET/CT			

Note: representative patient response only, may not be representative for all patients.



1. Imaging of prostate-specific membrane antigen with positron emission tomography.
2. Hope et al. JAMA Oncol. 2021.

# TLX250-CDx (Zircaix®<sup>1</sup>) for imaging of kidney cancer

A clear value proposition in the diagnosis of clear cell renal cell carcinoma (ccRCC)

## U.S. BLA filing submission complete

- Antibody-based PET imaging agent targeting CAIX (<sup>89</sup>Zr-girentuximab)
- Initial indication: Characterising renal masses as ccRCC
- FDA Breakthrough Therapy Designation, delivers on a major unmet medical need
- Highly positive Phase III data (ZIRCON study): Potential to change standard-of-care as a non-invasive tool for more confident decision making
- Recognised for the first time in EANM guidelines (April 2024) as an emerging technology for the management of RCC
- Potential first approved targeted radiopharmaceutical imaging agent for kidney cancer

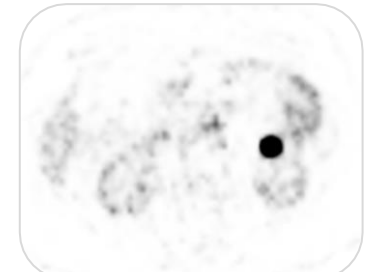
**\$500M+ initial U.S. opportunity, upside to \$750M+ from indication expansion to include staging and recurrence**



1. Brand name subject to final regulatory approval.

## TLX250-CDx PET (ZIRCON study)

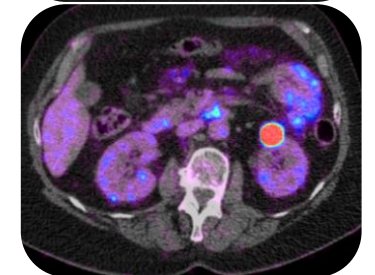
PET positive patient



Diagnostic CT



Fused PET/CT



*Patient representative sample - individual results may vary.*

# TLX101-CDx (Pixclara™<sup>1</sup>) for imaging of glioma

## Unmet need for delineating progressive disease from treatment-induced changes

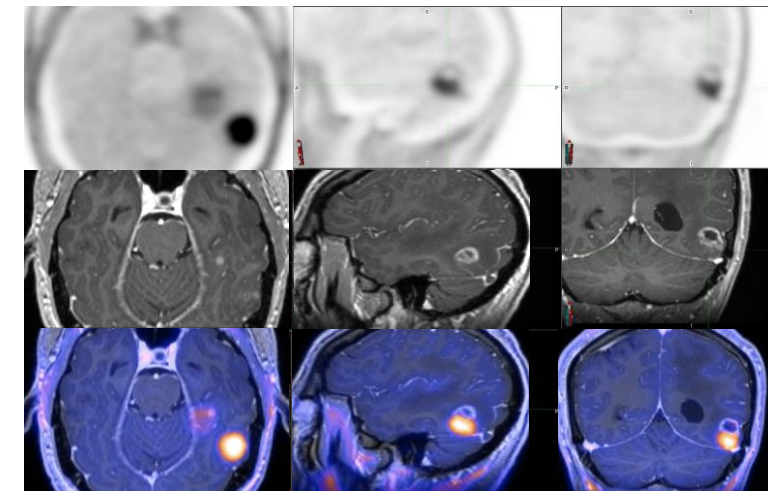
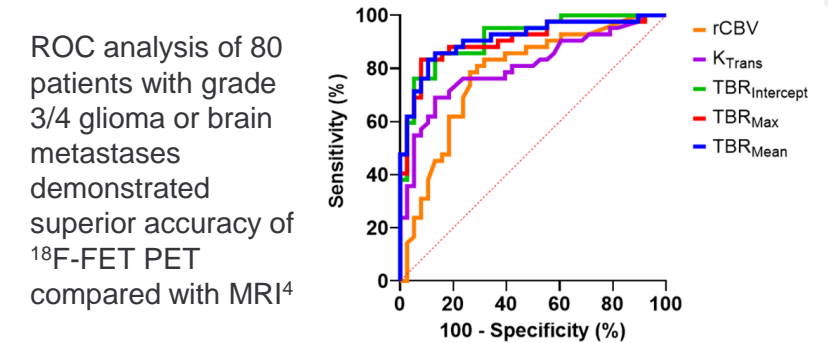
### Preparing to file U.S. NDA for TLX101-CDx (<sup>18</sup>F- floretyrosine)

- **Small molecule-based PET imaging agent targeting LAT1 & LAT2**
- **Initial indication:** Characterising recurrent glioma or treatment-induced change
- **FDA Fast Track and Orphan Drug Designations**, potential to meet major unmet need as a tool for management of progression/ treatment monitoring
- **Widely used in Europe and recommended** in the EANM/EANO/RANO/SNMMI guidelines for PET imaging of gliomas<sup>2</sup>
- **First PET-based response assessment criteria** for diffuse gliomas issued by RANO in January 2024<sup>3</sup>

**\$100M initial U.S. opportunity, upside to \$470M from indication expansion to include brain metastases**



1. Brand name subject to final regulatory approval.
2. Joint European Association of Nuclear Medicine//European Association of Neurooncology/Response Assessment in Neurooncology practice guidelines/Society for Nuclear Medicine and Molecular Imaging procedure standards for the clinical use of PET imaging in gliomas.
3. Albert et al. *Lancet Oncol.* 2024.
4. Veronesi et al. *J Nucl Med.* 2023.



*Note: Patient representative sample - individual results may vary.*



# CMS<sup>1</sup> proposal to improve payment for precision diagnostics

Facilitates continued patient access once pass-through expires

## Current situation

### Transitional pass-through (TPT)

- For three years, the cost of specialised diagnostics is paid separately by CMS for outpatients
- Post-TPT, the cost is bundled with the scan
- Results in specialised diagnostics being packaged with lower-cost products
- CMS overpays for low-cost products and reimbursement is reduced for higher-cost products
- Patients lose access to higher cost, specialised diagnostics

## CMS proposal (July 2024)

### Unbundled payment, effective January 2025

- Precision diagnostics with a per day cost >US\$630 will continue to be paid separately to Medicare outpatients following the expiry of TPT
- Facilitates more equitable and reliable access to advanced imaging for all patients, supports physicians to prescribe the most clinically appropriate solution
- Applies to Illuccix® and future Telix diagnostics, if approved – i.e. Zircaix®, Pixclara™ and TLX007-CDx
- **Final rule will be issued in early November 2024 following a 60-day comment period**

# Prostate cancer therapy: TLX591

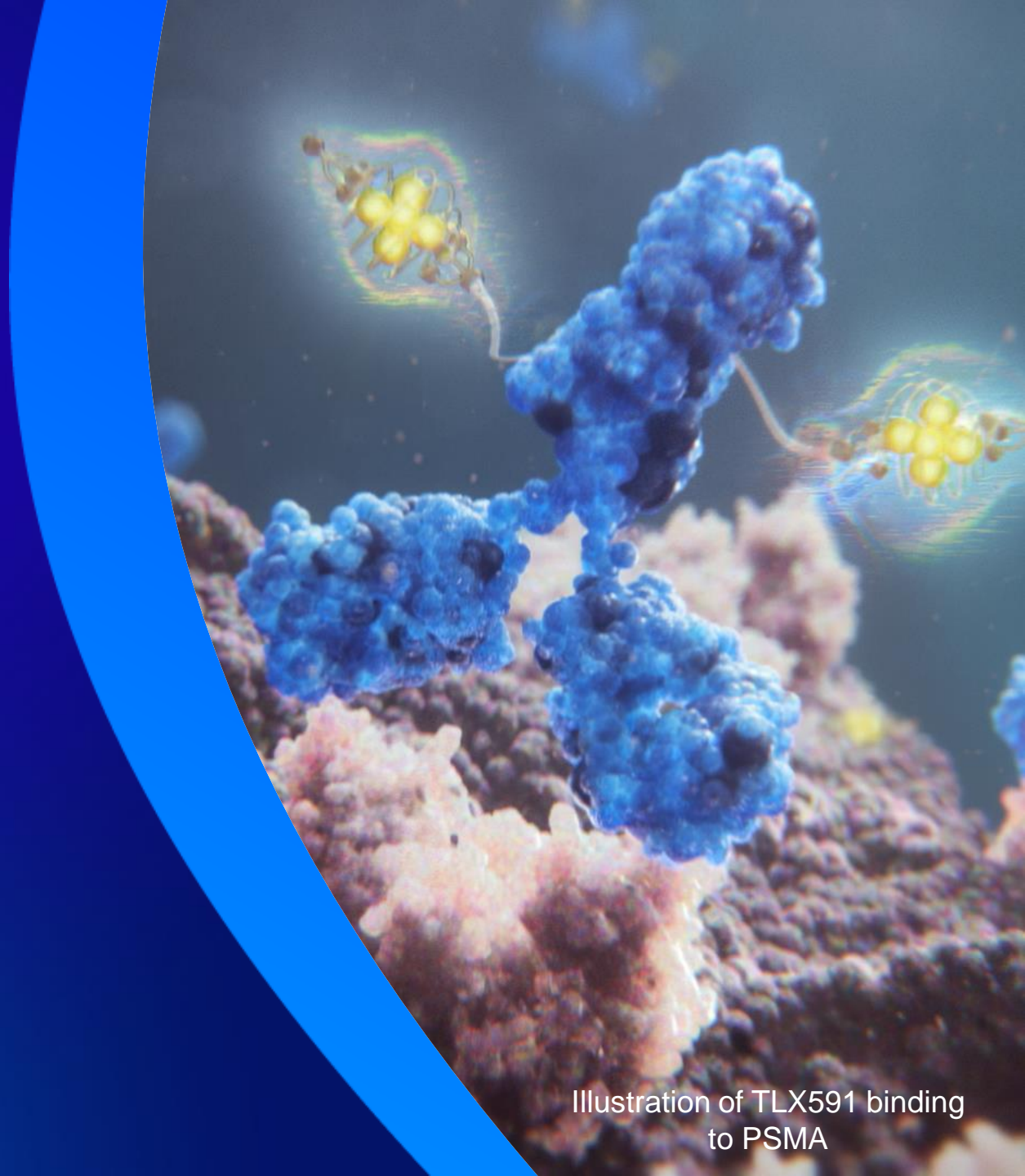
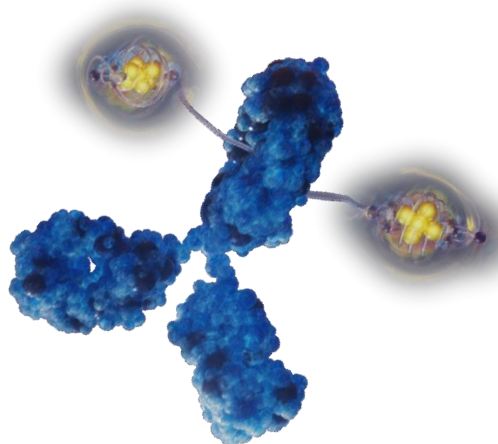


Illustration of TLX591 binding  
to PSMA

# TLX591: Highly differentiated PSMA targeting therapy

First-in-class / best-in-class radiopharmaceutical therapy using a biologic

TLX591:  
Lutetium ( $^{177}\text{Lu}$ )  
rosopatamab tetraxetan



## rADC for PSMA-expressing mCRPC

- PSMA is a validated target in prostate cancer<sup>1</sup>
- TLX591 utilises a **PSMA-targeted monoclonal antibody (mAb) approach**. mAbs are distinguished by their internalisation, long retention and functional selectivity for tumour-expressed PSMA<sup>2</sup>
- Short, patient-friendly dosing regimen and low occurrence of off-target side effects, while delivering a meaningful therapeutic index<sup>3</sup>
- ProstACT SELECT trial confirmed safety profile and rPFS of 8.8 months (favourable to small molecule agents at Phase I/II (same stage of development))<sup>1</sup>
- Multi-billion total addressable market, first PSMA therapy generated US\$980M in 2023 (first year of sales)<sup>4</sup>

# Potential to overcome limitations of small molecule approach

## Advantages of the rADC approach

### Potential benefits for patients, HCPs<sup>2</sup> and payors

#### DOSING FLEXIBILITY



Simple 2-dose regimen  
Lower cumulative radiation exposure: 152 mCi vs. 1200 mCi



Patient friendly, shorter treatment duration  
Drives mCRPC patient throughput; lowers per patient office visit cost  
Lowers patient and caregiver radiation exposure

#### PATIENT QUALITY OF LIFE



No renal toxicity, dry mouth, dry eye, ganglia irradiation observed in clinical trials



Improved outcomes/overall patient comfort  
Prevents costly renal toxicity treatment intervention

#### SURVIVAL



Promising overall survival demonstrated in early studies  
Median OS 42.3 months<sup>1</sup>



More effective treatment allows patients to live longer  
Improved payor treatment cost-effectiveness

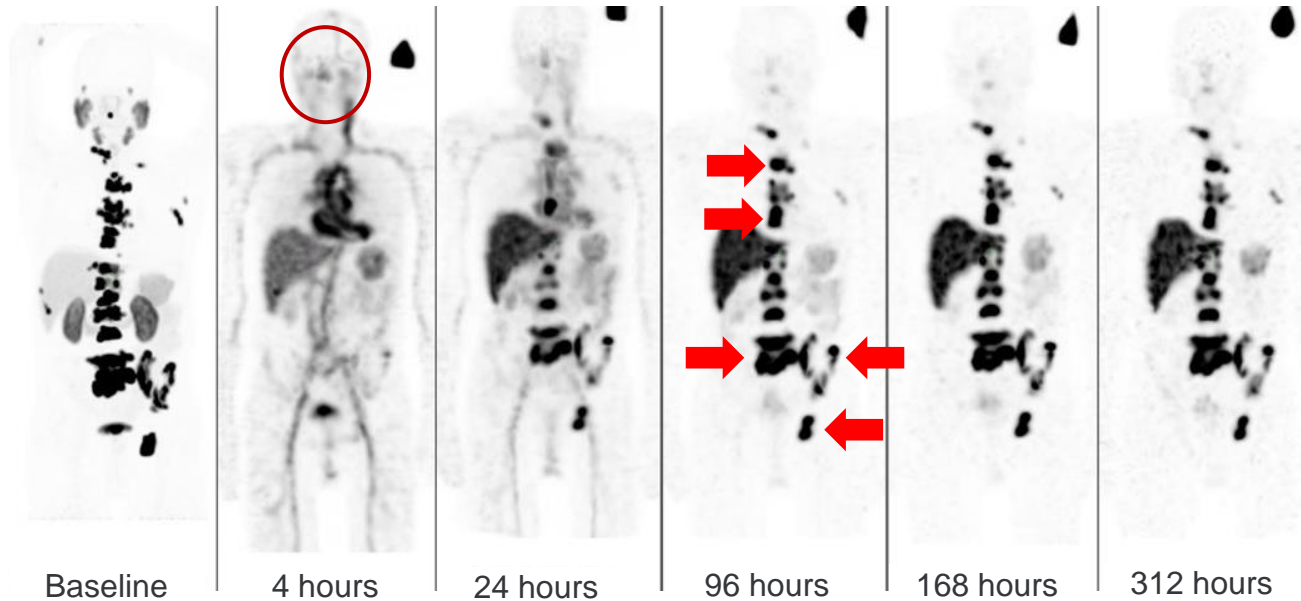


1. Tagawa, et al Cancer 2019 (Open label, single-arm Phase I/II clinical trial in 17 patients with advanced mCRPC).
2. Healthcare professionals.

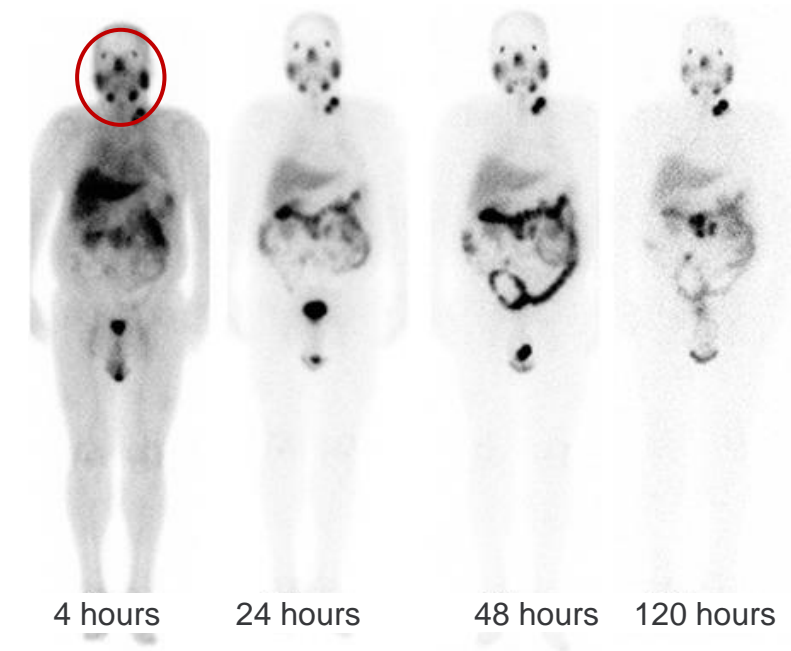
# Biodistribution: TLX591 vs <sup>177</sup>Lu-PSMA-617

Visually illustrates durable retention of TLX591 in target tumours

SPECT TLX591 biodistribution<sup>1</sup>



SPECT <sup>177</sup>Lu-PSMA-617 biodistribution<sup>2</sup>



Patient representative scans - individual results may vary.



1. Patient 9-005 ProstACT-SELECT study. Source data: Final Dosimetry report. August 2023.
2. 2017 Kabasakal et al. *Mol Imaging Radionucl Ther*. 2017 Jun; 26(2): 62–68. “Lu-177-PSMA-617 Prostate-Specific Membrane Antigen Inhibitor Therapy in Patients with Castration-Resistant Prostate Cancer: Stability, Bio-distribution and Dosimetry”.

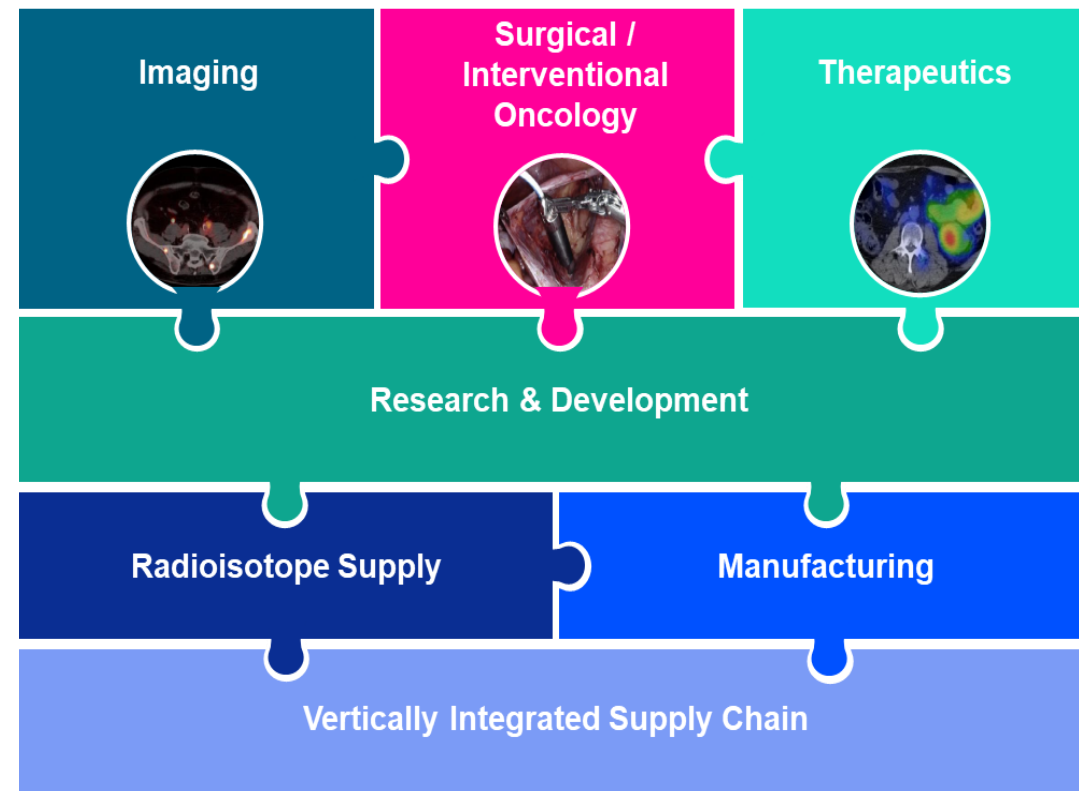
# Summary



# Telix is pioneering the next generation of radiopharmaceuticals

## Uniquely positioned in the fast-growing radiopharmaceutical industry

- Radiopharmaceutical industry is becoming a fundamental pillar of oncology – market size is forecast to **grow to US\$35bn by 2031**<sup>1</sup>
- Highly differentiated, **late-stage therapeutic assets** in prostate, kidney and brain cancer, with **multiple clinical milestones ahead**
- Growing commercial portfolio **underpinned by Illuccix®**, with regulatory filings progressing across three additional diagnostic products
- Strong **revenue growth** (Q2 2024 revenue: A\$189m) and **cash generation** is funding development of the pipeline
- World-class supply chain and **vertically integrated** manufacturing capability



# Contact details:

Kyahn Williamson

SVP Investor Relations and  
Corporate Communication

[kyahn.williamson@telixpharma.com](mailto:kyahn.williamson@telixpharma.com)

