H1 2023 Results and Business Update

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Telix Pharmaceuticals (ASX:TLX)

Bell Potter Emerging Companies: 12 September 2023

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Delivering on the promise of precision medicine through targeted radiation

Positive ZIRCON Ph III readout, delivers on a major unmet need in diagnosis of ccRCC

Pipeline and technology expansion through acquisitions and in-licensing

A transformational 12 months

Highly successful Illuccix® launch

Transition to cash flow positive

Multiple trials underway advancing our therapeutic pipeline

Continued enhancement of supply chain, manufacturing and development capabilities

Driven by our purpose to help people with cancer and rare diseases live longer, better quality lives

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Financial highlights

Telix has rapidly transitioned to a sustainable commercial business

- Continued strong revenue growth since commercial launch of Illuccix in H1 2022
- Earnings (Adjusted EBITDAR[1]) demonstrates the profitability of the commercial organisation
- Costs continue to reduce as a percentage of revenue, indicative of commercial performance and expenditure control
- Operating cash flow positive, while funding commercialisation activities to launch two new imaging products[2]

REVENUE

Up 820% to $220.8M ($24.0M, H1 2022)

EARNINGS[1]

Up $110.4M to $82.4M ($28.0M loss, H1 2022)

OPERATING CASH FLOW POSITIVE

$131.7M as at 30 June 2023 ($116.3M as at 31 Dec 2022)

REDUCED NET LOSS

Reduced 80% to $14.3M loss including non-cash adjustment

1. Earnings before interest, tax, depreciation, amortisation, research and development, non-cash remeasurement of provisions and other income and expenses.
2. Subject to regulatory approval.

Core pipeline: Oncology and rare diseases

Prostate	PSMA[1]	PHASE 1	PHASE 2	PHASE 3	COMMERCIAL	
Small molecule	^{68}Ga	TLX591-CDx (^{68}Ga-PSMA-11, Illuccix®)				Imaging
Antibody	^{177}Lu	TLX591 (^{177}Lu-rosopatamab)				Therapy
Kidney	**CAIX[2]**	**PHASE 1**	**PHASE 2**	**PHASE 3**	**COMMERCIAL**	
Antibody	^{89}Zr	TLX250-CDx (^{89}Zr-girentuximab)				Imaging
Antibody	^{177}Lu	TLX250 (^{177}Lu-girentuximab)				Therapy
Brain	**LAT-1[3]**	**PHASE 1**	**PHASE 2**	**PHASE 3**	**COMMERCIAL**	
Small molecule	^{18}F	TLX101-CDx (^{18}F-FET)				Imaging
Small molecule	^{131}I	TLX101 (^{131}I-IPA)				Therapy
BMC/RD[4]	**CD66[5]**	**PHASE 1**	**PHASE 2**	**PHASE 3**	**COMMERCIAL**	
Antibody	^{99m}Tc	TLX66-CDx (^{99m}Tc-besilesomab, Scintimun®)				Imaging
Antibody	^{90}Y	TLX66 (^{90}Y-besilesomab)				Therapy

1. Prostate-specific membrane antigen.
2. Carbonic anhydrase IX.
3. L-type amino acid transporter 1.
4. Bone marrow conditioning/rare diseases.
5. Cluster of differentiation 66.

Note: Shaded sections indicate expected development stage in the next 12 months.

Clinical development highlights

Progress across multiple therapeutic trials

CAIX PROGRAM (INCLUDING RENAL CANCER)	STARBURST and STARSTRUCK FPI	STARLITE-1 & 2 screening patients	ZIRDOSE-CP (China) FPI	OPALESCENCE complete
PROSTATE CANCER THERAPY	30 patients dosed in ProstACT SELECT	SELECT data readout Q4 2023	ProstACT GLOBAL open, dosing imminent in A/NZ	GLOBAL US IND filing Q4 2023
GLIOMA IMAGING AND THERAPY	IPAX-2 FPI, six sites screening across ANZ / EU	IPAX-Linz surpassed 70% enrolment	IPAX-China study approved	Preparing global label-indicating study for TLX101
RARE DISEASES PROGRAM	Radiolabelled olaratumab POC, progressing to first-in-human trials	Preparing AU sites for Phase II study of TLX66 in AML[1]	Preparing for patient dosing in study of TLX66 in pediatric leukemia	

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1. Acute myeloid leukemia.

Growth strategy

Delivering long-term benefit to shareholders and patients

Commercialise the diagnostics portfolio

Revenue from first product growing

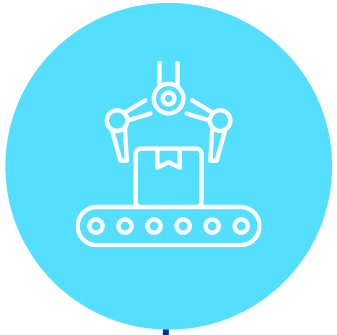
Two additional imaging products advancing towards regulatory filing

Unlock value in the therapeutic pipeline

Clinical milestones across multiple programs

Market opportunity growing as radiopharmaceuticals move into the “mainstream”

Strengthen supply chain and manufacturing



Expanding in-house capabilities in U.S. & EU

Strengthens barrier to entry through control of manufacturing scale-up and process development

Expand the pipeline

Robust program evaluating new targets and technologies

Leveraging our track record in identifying and commercialising promising assets to build future pipeline

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Four major focus areas in 2023

Strong progress across all major value creating catalysts

✓

Illuccix® - continued revenue growth and global rollout

H2

Biologics License Application (BLA) submission for TLX250-CDx

H2

New Drug Application (NDA) for brain cancer imaging (TLX101-CDx)

H2

ProstACT GLOBAL patient recruitment and ProstACT SELECT data readout

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Illuccix® for prostate cancer imaaging

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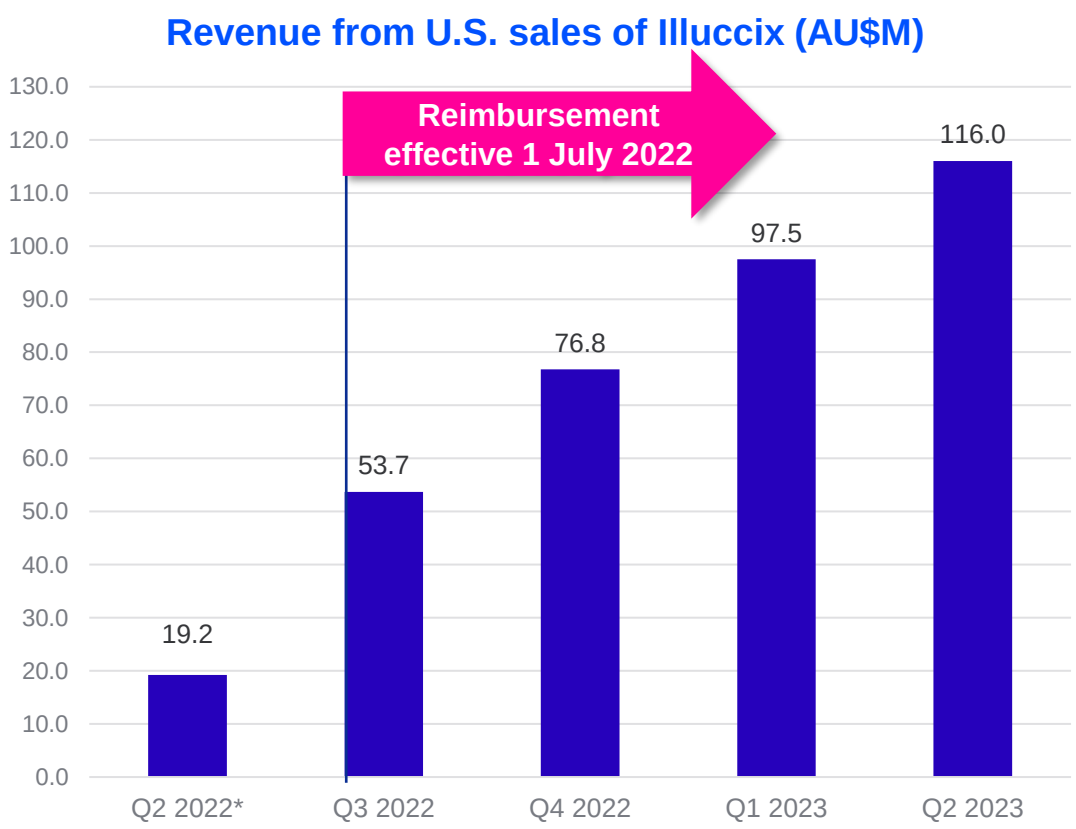
Illuccix for prostate cancer imaging

Strong performance in the growing PSMA PET-CT market



- Commercially available in U.S., Canada, Australia and New Zealand
- >200 points of distribution in the U.S.
- Strong customer base across all segments
- Growth driven by account expansion and increased awareness

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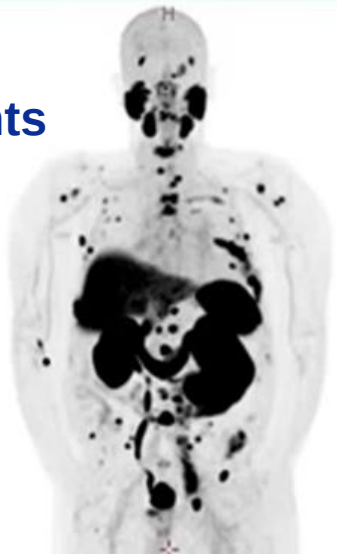
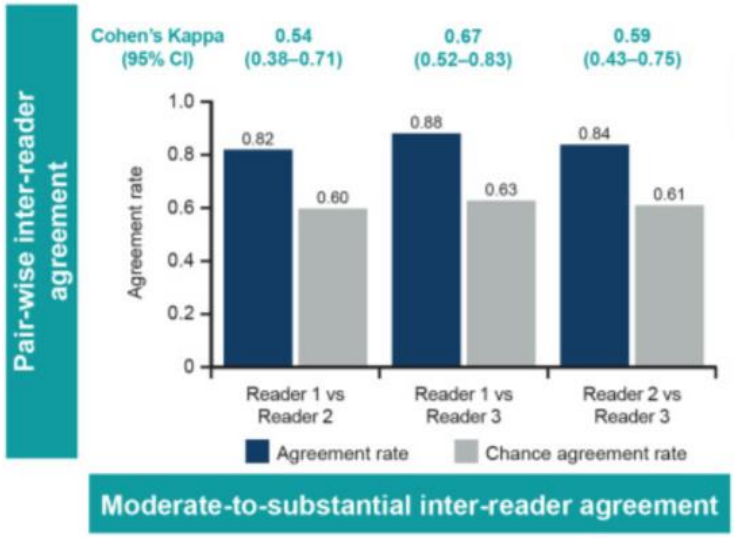
The Illuccix difference

Clinical accuracy + optimum scheduling flexibility

New scientific publications and guidelines illustrate ^{68}Ga-PSMA-11 PET/CT has validated accuracy compared to other PSMA imaging agents

Using the ^{18}F-labelled compounds [^{18}F]F-PSMA-1007 and [^{18}F]F-rhPSMA-7.3, interpretation of bone lesions is more challenging compared to [^{68} Ga]Ga-PSMA-11 [24, 125, 127, 128]. A number of benign bone lesions accumulate PSMA and result in false positives on PSMA-PET/CT, including fractures, osteophytes, benign bone lesions (fibrous dysplasia, hemangioma), or unknown etiology.





High true positive rates of detection for regional and distant metastases including bone[1-3]

Established excellence in diagnostic performance even for micro metastatic disease[4]

Accurate interpretation with high reproducibility and inter-reader agreement[6-7]

1. Rauscher et al. *J Nucl Med.* 2020. 2. Kroenke et al. *J Nucl Med.* 2021. 3. EANM/SNMMI procedure guidelines for prostate cancer imaging 2.0 (Jan 2023). 4.Phelps et al. *J Nucl Med.* 2022. 5. Image courtesy of BAMF Health. 6. Kuo et al. *J Nucl Med.* 2023. 7. EANM/SNMMI procedure guidelines for ^{177}Lu-PSMA-RLT (May 2023).

PSMA PET imaging market

Guidelines and evolving clinical practice and evidence driving market expansion

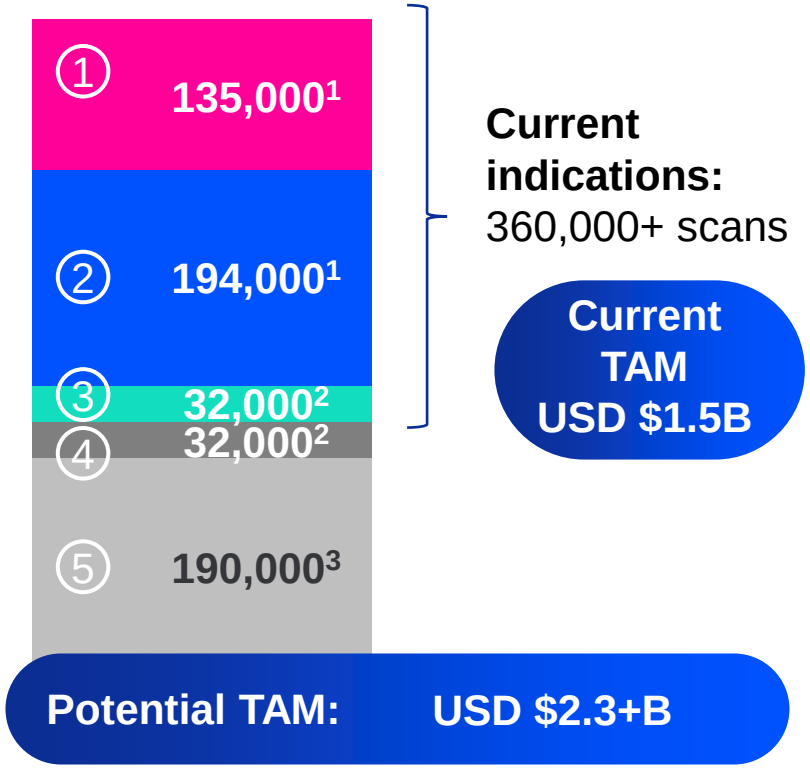
Current indications

1. Initial staging for suspected metastases (NCCN, AUA)
2. Suspected recurrence (NCCN, AUA)
3. Patient selection for radioligand therapy (NCCN, AUA)

Potential clinical utilisation (guideline evolution)

4. Monitoring response to radioligand therapy
5. Monitoring for progression in nmCRPC and mCRPC (AUA)

U.S. Total Addressable Market (TAM)
580,000+ scans

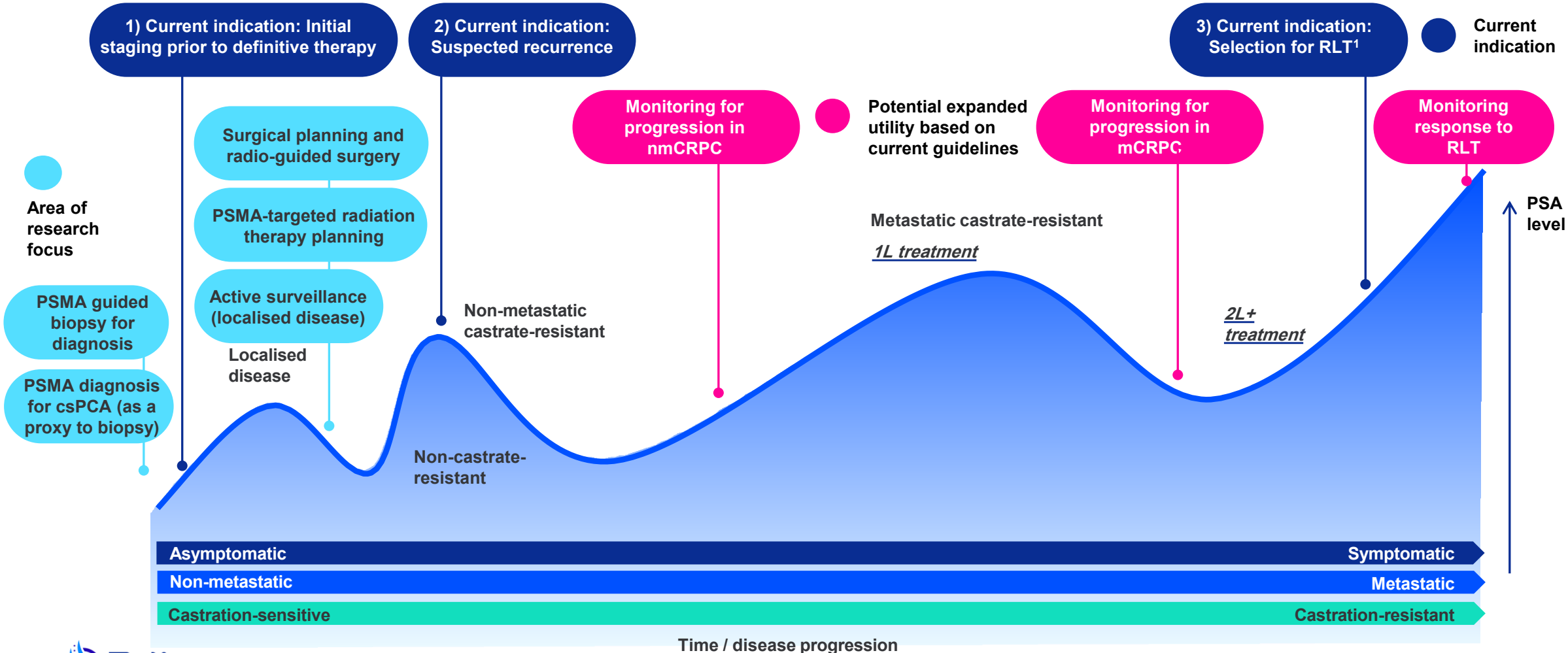


1. ACS. Cancer Facts & Figures 2023. Atlanta, GA: American Cancer Society; 2023; Scher 2015, PLoS1; Nezolosky 2018, Journal of Clinical Oncology; Dinh 2016, Urology.
2. Tessellon PRECISE database, accessed July 2023.
3. Tessellon PRECISE database, accessed July 2023; Saad 2021, Prostate Cancer and Prostatic Disease.

Note: Dollar ($) values are management estimates based on ACS (US).

Potential to expand the clinical utility

Guidelines and clinical research highlight potential across the patient journey

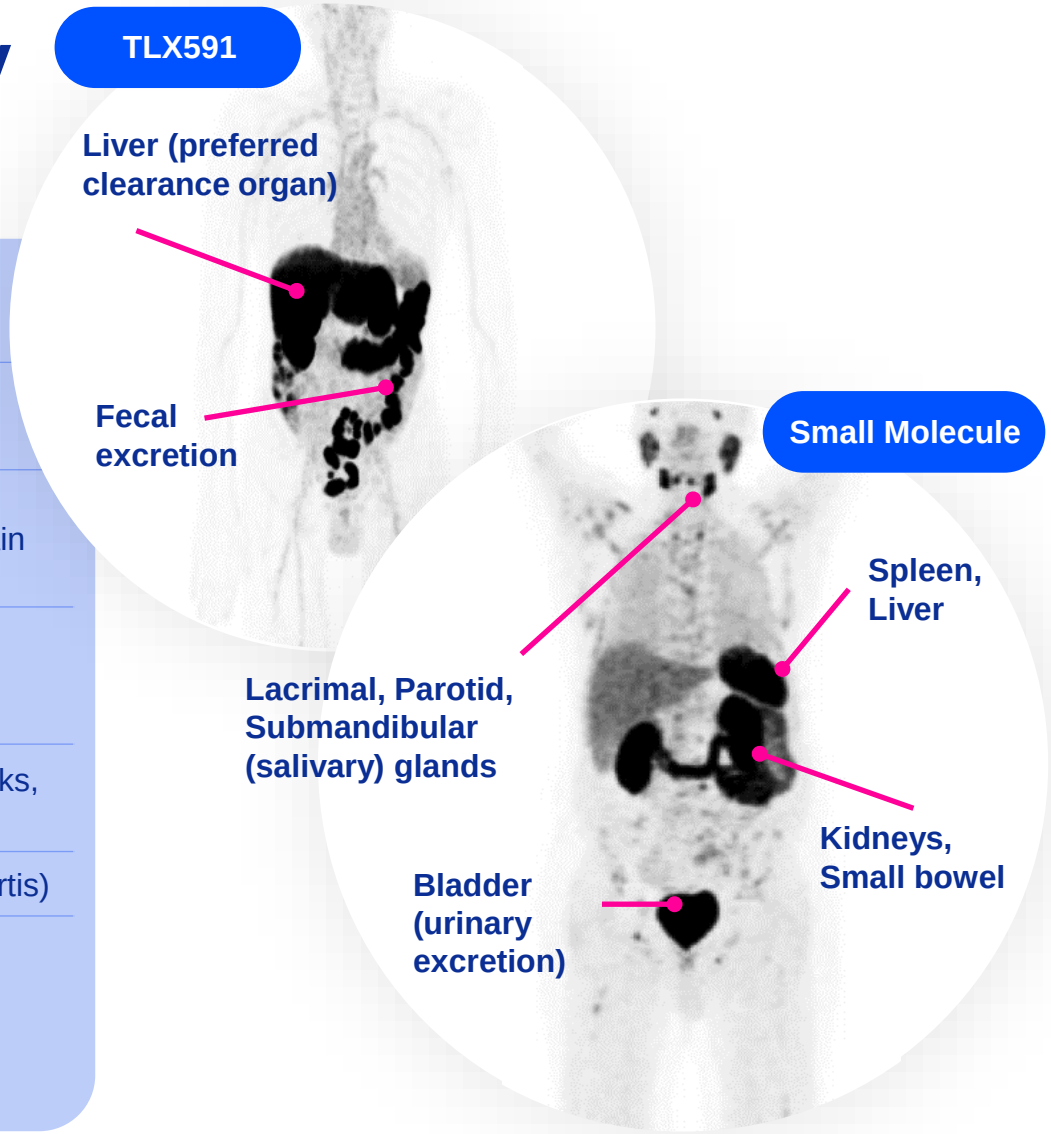


1. Radioligand therapy

TLX591: Differentiated PSMA therapy

Potential advantages of the antibody approach

Antibody (TLX591)	Small Molecule
Functionally specific for tumour-expressed PSMA, does not “hit” most endogenous PSMA	Taken up by endogenous PSMA
Reduced off-target radiation, reduced potential for undesirable side-effects[1]	Off-target effects impact quality of life, including dry eye, xerostomia and back pain from ganglia irradiation
Longer circulation time and tumour retention, cleared in the liver and excreted, allowing for fewer doses[2]	Rapidly excreted via the urinary tract
Shortest dosing regimen of all PSMA therapies, two x 76mci doses, 14 days apart	Dosing regimens range from 24 to 36 weeks, at up to 200mci per dose
Approved products: N/A	**Approved products:** PLUVICTO® (Novartis)
Products in development: • TLX591	**Products in development:** • ^{177}Lu-PNT-2002 (Point Biopharma) • ^{177}Lu-PSMA-I&T (Curium)



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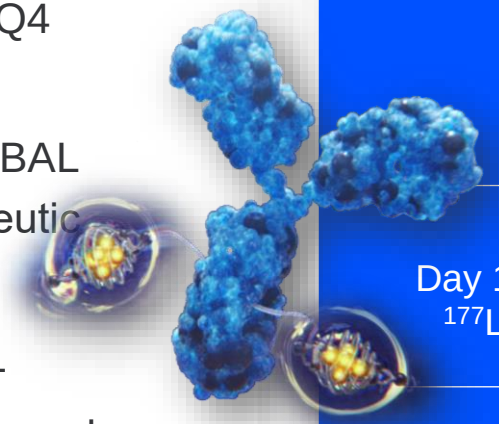
1. New Class of Radiopharmaceutical Therapy Makes Headway in Prostate Cancer (onclive.com).
2. Sun, Michael et al.. Curr Oncol Rep.

ProstACT SELECT study: Enrolment complete

Correlation between imaging and therapy to optimise patient selection

- ProstACT SELECT (NCT04786847) readout expected in Q4 2023
- Designed to enhance patient selection for ProstACT GLOBAL and support indication expansion for Telix's PSMA therapeutic portfolio, based on a "theranostic" approach
- In a patient population consistent with ProstACT GLOBAL
- **Primary endpoint:** Determine whole body biodistribution and organ radiation dosimetry of tracer levels of administered activity of TLX591 (^{177}Lu-rosopatamab)
- **Secondary objective:** Confirm favourable and selective uptake of TLX591 in PSMA-expressing tumours as determined by suitable tumour-to-heathy tissue ratios and residence times



30 patients dosed

Day 1: First dose ^{177}Lu-TLX591

Days 1-13: Safety evaluation, imaging with ^{68}Ga-PSMA-11

↓

Day 14: Second dose of ^{177}Lu-TLX591 upon confirmed safety

↓

Image comparison to assess biodistribution and dosimetry, safety and tolerability following each dose

Data readout Q4 2023 + ProstACT GLOBAL enrolling patients

TLX250-CDx: Renal cancer imaging

Regulatory filing and preparation for commercial launch underway

- **ccRCC[1] is the most common and aggressive form of kidney cancer**
- Based on Phase III data TLX250-CDx has the potential to change standard of care in the diagnosis and management of renal masses and ccRCC
- **Primary endpoint met:** Sensitivity of ≥84% and specificity of ≥84% in all three readers (86% / 87% overall)
- An effective non-invasive tool for more confident decision making
- Delivers on a major unmet medical need; granted FDA Breakthrough Therapy designation

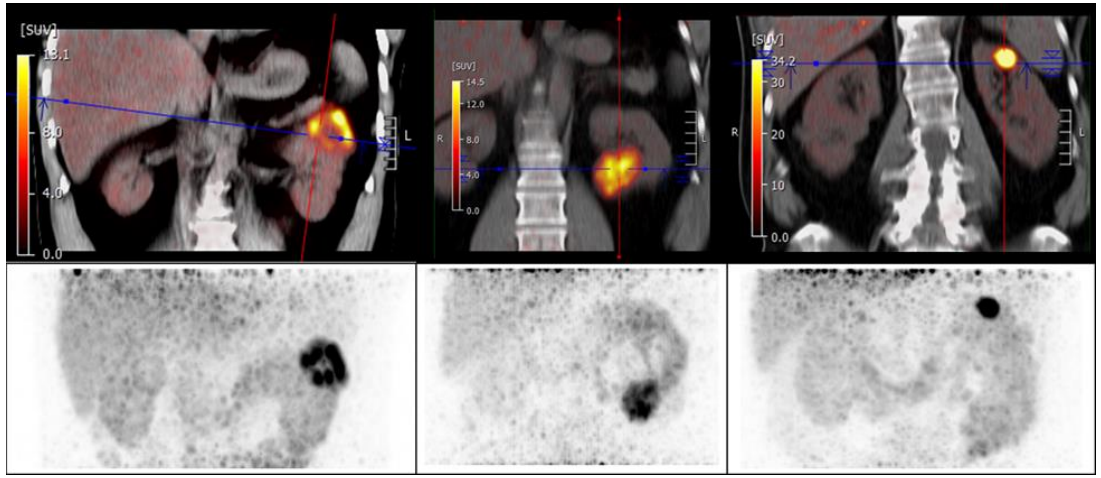
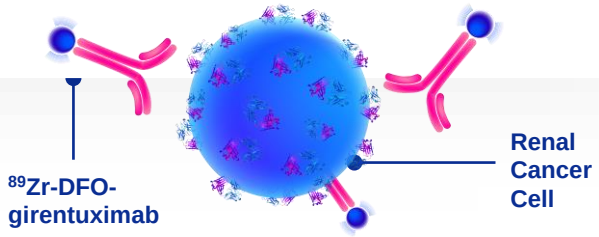


Figure 1: CAIX targeted PET/CT with ^{89}Zr-DFO girentuximab enables the visualisation and characterisation of renal masses with great image contrast. ^{89}Zr-DFO girentuximab exhibits high uptake in clear cell renal carcinoma lesions (SUVmax range 11-86) and low background activity in the normal renal parenchyma and other normal organs.[3]

Patient representative sample - individual results may vary.



1. Clear cell renal cell carcinoma
2. ASX disclosure 7 November 2022.
3. ASX disclosure 1 May 2023.

TLX250-CDx: U.S. market opportunity

Identification and characterisation of ccRCC

New incidental renal mass

- Estimated 73,994 incidental findings
- Over 1/3 of IDRMs are non-ccRCC[1]
- >45% of small renal masses <1cm are benign[2]

Renal cancer diagnosis

- 79,000 patients will be diagnosed with RCC in 2022 in the U.S.[3]
- 80% of patients with RCC are clear cell[4]
- Over 60% of ccRCC is found incidentally[5]

Of total patient population ~ 110,000 expected to be suitable for imaging with TLX250-CDx

Initial addressable market

>US$500M

in the U.S.

Active surveillance for known renal mass

- Prevalence unknown
- Active surveillance is recommended for patients with select renal masses (e.g. older patients, <2cm)
- A 6-monthly, then annual, CT/MRI scan is currently recommended in the NCCN Guidelines® kidney cancer v3.2023

Previously treated ccRCC high risk

- 599,000 patients living with kidney cancer in the U.S.[3] in 2019

Note: TLX250-CDx pricing estimate based on Illuccix.

1. Telix: Data on file from ZIRCON study (patients with IDRM diagnosed every year).
2. Johnson et al., 2015.
3. SEER. (2022). Cancer Stat Facts: Kidney and Renal Pelvis Cancer: https://seer.cancer.gov/statfacts/html/kidrp.html.
4. STATPEARLS Rahul D. Arora 2020;11(3):79-87.
5. Vasudev et al. BMJ 2020.

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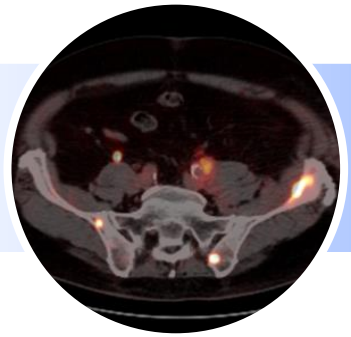
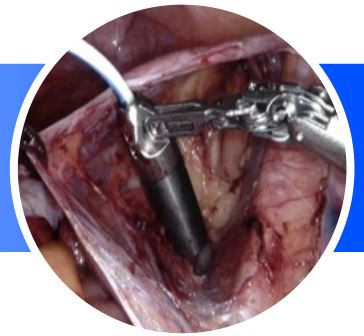
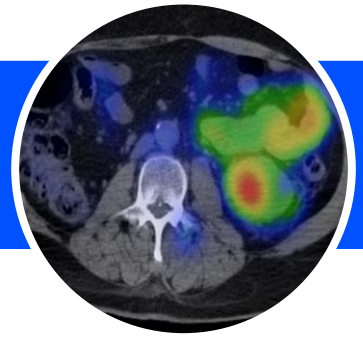
Leadership in urologic oncology

Building deep relationships with the Illuccix® customer

Supporting the urologic patient across the continuum of imaging, surgery and therapy







Diagnosis & Staging

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

TLX250-CDx

Surgical Technologies

Lightpoint MEDICAL

Therapy

PROSTACT GLOBAL

STARLITE

Telix AI™

Telix

TLX101-CDx for imaging of glioma (^{18}F-FET PET)

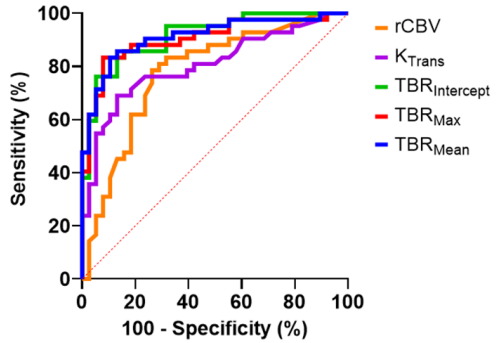
PREPARING TO LAUNCH IN 2024

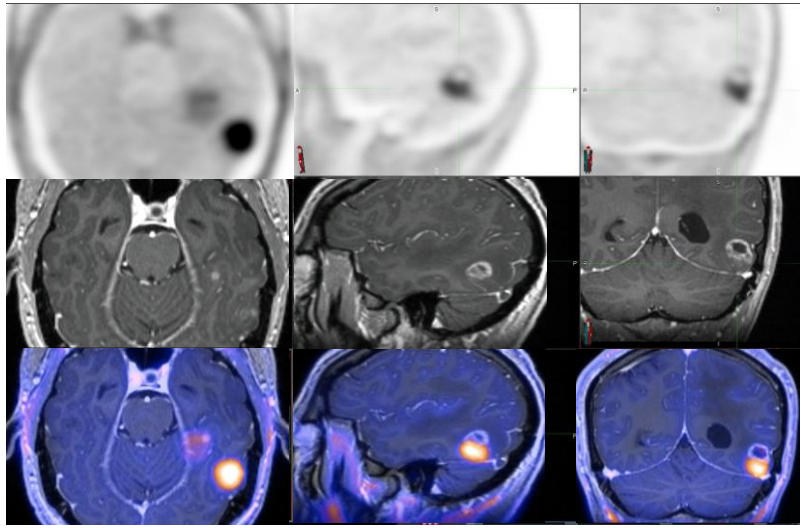
Unmet need for delineating progressive disease from treatment-induced changes

U.S. New Drug Application (NDA) in progress:

- **Initial indication:** Characterising recurrent glioma or treatment-induced change
- ~US$90M[1] initial U.S. market opportunity
- **Clear value proposition** as a potential tool for management of progression/ treatment monitoring
- **Orphan drug designation,** potential to meet major unmet need
- **Widely used in Europe and recommended** in the EANM/EANO/RANO/SNMMI guidelines for PET imaging of gliomas[3]

ROC analysis of 80 patients with grade 3/4 glioma or brain metastases demonstrated superior accuracy of ^{18}F-FET PET compared with MRI[4]





Patient representative sample - individual results may vary.

1. Dollar ($) value is management estimate based on U.S. reported incidence; assumes 1-2 scans per patient as a baseline.
2. Pharma Intelligence 2023 / SEER 2019: U.S. reported incidence for gliomas (annual).
3. 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.
4. Veronesi et al. *J Nucl Med.* 2023.

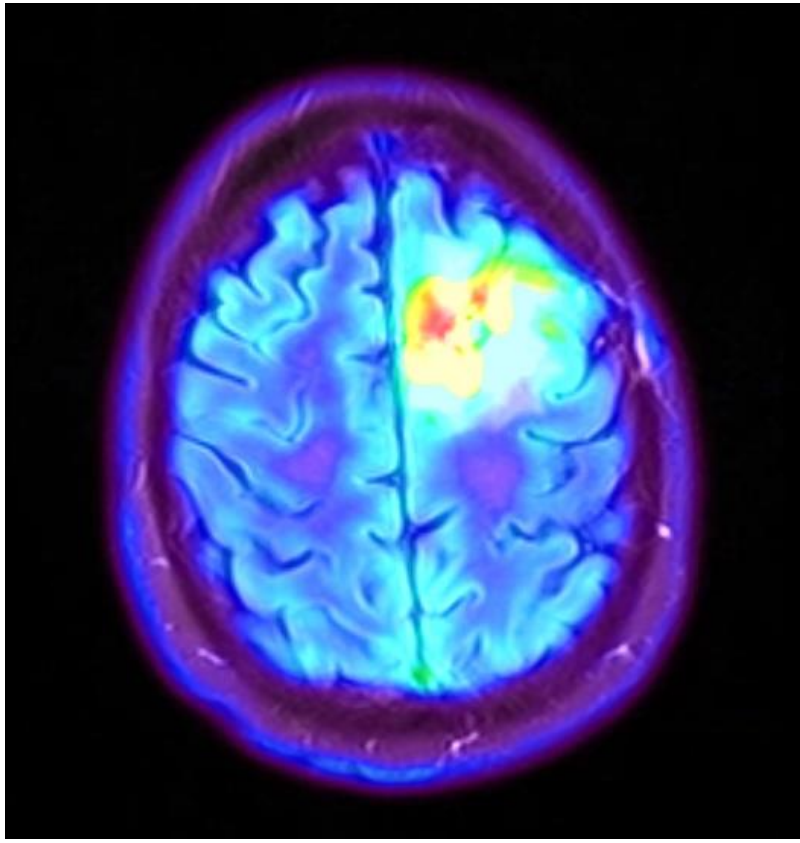
TLX101: Further studies progressing

Promising data warrants investigation in a front-line setting

- IPAX-1 multi-centre Phase I trial of TLX101 in combination with EBRT in patients with recurrent glioblastoma multiforme (GBM) completed in 2021
- Final data released in 2022 confirmed safety and tolerability profile, encouraging preliminary efficacy for further evaluation, based on 10 patients
- Evidence of potential anti-tumour effect from both imaging and clinical assessment
- Median overall survival (OS) of 13 months from the initiation of treatment in the recurring setting, or 23 months from initial diagnosis

Clinical development focus

- Sites initiated in IPAX-2 follow on study (Phase I arm) in front line setting (newly diagnosed patients) – *dosing patients*
- IPAX-Linz (Phase II, IIT[1]) treating patients in Linz, Austria, continued access for second-line patients – *surpassed 70% enrolment*
- IND accepted for review by NMPA[2] (China) - first therapy trial with Grand Pharma



PET/CT scan visualising an area of post-treatment necrosis

1. Investigator initiated trial
2. National Medical Products Administration.

Recent and upcoming milestones

Four key catalysts

- Illuccix® - continued revenue growth and global rollout
- ProstACT GLOBAL patient recruitment and data readout ProstACT SELECT
- BLA submission for TLX250-CDx
- NDA for brain cancer imaging (TLX101-CDx)

EXPECTED MILESTONES 2023

H1 2023 Achievements

- Illuccix® US label expansion and EU resubmission
- Olaratumab (TLX300) demonstrates theranostic proof of concept
- Brussels South (Seneffe) manufacturing facility operational
- TLX250 therapy + Merck KGaA DDRi combination study launch
- STARBURST study exploring TLX250-CDx in solid tumours launched
- IPAX-2 (TLX101 GBM therapy) patient dosing, IPAX-L continued enrolment
- Prostate and renal imaging bridging studies commence in China

Upcoming

- STARLITE-1 (TLX250 therapy) patient dosing and STARLITE-2 continued enrolment
- ZiP-UP and OPALESCENCE studies of TLX250-CDx complete
- Lightpoint Medical acquisition complete
- Illuccix Brazil approval decision
- CUPID study of TLX592 fully enrolled
- Regulatory filing Telix AI™
- TLX66 therapy study launch in AML

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